

REPROCESSING GUIDELINES

for Basic Neonatal Resuscitation Equipment
in Resource-Limited Settings



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Photo credits on cover: (top) PATH/Jillian Zemanek, (bottom left) PATH/Manjari Quintanar Solares, (bottom right) PATH/Evelyn Hockstein

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ACRONYMS

HBB	Helping Babies Breathe
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HLD	High-level disinfection/high-level disinfect
MEC	Minimum effective concentration
NaDCC	Sodium dichloroisocyanurate
PPE	Personal protective equipment
TP	Total parts

PURPOSE AND DEVELOPMENT OF THIS GUIDE

This guide is an in-depth resource on reprocessing of basic neonatal resuscitation equipment. Reprocessing is a multi-step process to clean and either sterilize or disinfect reusable medical equipment in order to make it safe for use on the next patient. The guidelines described here provide a variety of options for the reprocessing of basic neonatal resuscitation equipment that are feasible in different types of facilities in resource-limited settings.

Because single-use equipment cannot withstand the same level of reprocessing as reusable equipment and should be discarded after one use, **this guide discusses reusable neonatal resuscitation equipment only and is not intended for reprocessing of single-use equipment.** References to suction devices in this guide refer only to reusable suction bulbs or penguins. Suction bulbs which cannot be opened for cleaning should be discarded after single-use. This guide was created to support the Helping Babies Breathe (HBB) curriculum and thus focuses on the equipment used during basic neonatal resuscitation. For this reason, this guide does not include any guidance on suction machines or suction catheters.

This guide contains:

- **An overview of reprocessing materials and equipment.**
- **Space planning and workflow.**
- **Detailed step-by-step reprocessing instructions for each piece of equipment.**
- **Training and supervision considerations.**
- **Further considerations for health facility administrators and ministry of health officials.**

The target users of this guide are health or central processing or custodial workers who are responsible for reprocessing neonatal resuscitation equipment, as well as trainers, supervisors and other officials responsible for creating policies and planning resources for neonatal health. The guide serves as a training resource and a reference document. The associated job aid (<http://www.path.org/publications/detail.php?i=2601>), along with the appendices of this guide, are intended to be quick reference guides that can be posted in the reprocessing space in the health facility. Some information is repeated intentionally in different sections of this guide to allow users to adapt this guide to their specific needs and find information more easily.

The recommendations in this guide were based on the best available evidence as of November 2015, including the findings from an assessment¹ conducted by PATH in 2015 that helped better understand and characterize reprocessing practices for basic neonatal resuscitation equipment in resource-limited settings. When no literature was found, a consensus process amongst selected experts of the Neonatal Resuscitation Working Group of the UN Commission on Life-Saving Commodities for Women and Children was used to agree on recommendations. Two process leaders gathered materials and made recommendations based on available evidence. Consensus group members then reviewed the evidence, discussed, and voted on the final recommendations. To conclude the process, feedback received from external experts was incorporated into this guide.

SECTION 1

INTRODUCTION

Birth asphyxia, defined as the failure of the newborn to establish breathing immediately after birth, is one of the results of adverse intrapartum events and is a leading cause of neonatal death that kills 662,000 newborns every year, accounting for almost a quarter of all newborn deaths.² More than 98% of these deaths occur in low- and middle-income countries. Further, approximately 10 million babies do not breathe immediately at birth, and as many as six million require bag-and-mask resuscitation. Birth asphyxia is an important cause of neonatal death which can often be prevented by providing basic neonatal resuscitation.³

During use, resuscitation equipment becomes contaminated from maternal and neonatal bodily fluids, posing a risk of infection for the next infant who requires resuscitation if the equipment is used without appropriate reprocessing or after improper storage. This risk is of particular concern in newborns since they are much more vulnerable to infection than older children and adults.⁴ Like all reusable medical equipment, neonatal resuscitation equipment must undergo a thorough, multi-step process known as “reprocessing” to clean and either sterilize or high-level disinfect (HLD) and properly store it in order to make it safe for use on the next patient.⁵

Any object in a health facility can become contaminated with pathogenic microorganisms and serve as a vehicle for transmission of nosocomial infections.⁶⁻⁸ Examples in the literature include neonatal resuscitation equipment. In developing countries, nearly 50% of early-onset neonatal bloodstream infections are due to gram-negative bacteria, such as *Klebsiella*, *Pseudomonas*, and *Acinetobacter*. These gram-negative bacteria are known to cause outbreaks from the same source because they flourish in multiple-use containers of medications, liquid soaps, other solutions (including antiseptics and disinfectants), and on insufficiently reprocessed or improperly stored medical equipment.⁹

Adequate reprocessing of medical equipment and thorough cleaning of the health facility environment are essential to helping newborns survive and are relatively simple ways in which we can protect newborns from acquiring infections while in the facility.

The appropriate reprocessing method for reusable medical equipment depends upon the level of infection risk posed by the object. The Spaulding Classification System, which outlines the risk of transmission of infection posed by medical devices and equipment, divides equipment and devices into three categories: critical items, semi-critical items, and non-critical items.^{10,11} The type of body tissue in/on which the equipment will be used (e.g., inside a sterile space like a vein, or in contact with mucous membranes like the respiratory tract) determines the need for sterilization, HLD, intermediate-level disinfection, or low-level disinfection. Respiratory therapy equipment, including resuscitation equipment, is classified as semi-critical, meaning that the equipment should be free from all microorganisms, but a small number of bacterial spores are permissible.^{10,11} Therefore, at a minimum, resuscitation equipment must undergo HLD. However, because newborns are more vulnerable than older children and adults, sterilization is the desired process, whenever possible, as it gets rid of all microorganisms and spores.

Each step in the reprocessing sequence for neonatal resuscitation equipment has a specific purpose. **Steps need to be followed in the correct order** to protect not only the newborns resuscitated with the equipment, but also the health workers who are tasked with reprocessing.

Overview of Reprocessing Steps for Neonatal Resuscitation Equipment

There are four main stages involved in reprocessing neonatal resuscitation equipment: PREPARATION, PRE-DISINFECTION, DISINFECTION, and POST-DISINFECTION. Each stage involves one or more reprocessing steps. The detailed description on how to carry out each step can be found in **Section 4 (Reprocessing Steps)**. This overview will help orient the reader to the purpose of each reprocessing step:

1 PREPARATION STAGE

In order to begin reprocessing as soon as resuscitation equipment is no longer being used, all the materials, equipment, and space needed to conduct reprocessing must be ready in advance. Preparing the reprocessing space and equipment in advance also helps prevent transmission of microorganisms from the patient care area into the reprocessing area.

Equipment should be reprocessed as soon as it is no longer needed at the bedside. If bodily fluids are allowed to dry on the equipment, they are more difficult to remove and interfere with effective sterilization or HLD. Moreover, dry organic matter leads to unnecessary discoloration and equipment damage.

2 PRE-DISINFECTION STAGE

IMMEDIATE PRE-CLEANING: To protect the health worker performing the reprocessing, resuscitation devices are wiped externally to decrease the possibility of contamination. After resuscitation equipment is used, microorganisms such as hepatitis B virus (HBV), hepatitis C virus (HCV), and the human immunodeficiency virus (HIV) may be found on the equipment and may contaminate the health worker while handling equipment. This process requires a chlorine solution 0.5%.

NOTE: in some reprocessing guidelines, the term “decontamination” is used to refer to this step. However, it has been observed that the term “decontamination” is easily confused with “disinfection”, which is a separate process. Therefore, the term “immediate pre-cleaning” is used to reduce confusion between this step and the disinfection step.

DISASSEMBLY: To expose all equipment surfaces to the cleaning and sterilization or disinfection method, the equipment must be completely disassembled. This will allow for successful sterilization or HLD. Even though the resuscitation equipment may not appear dirty, it can harbor microorganisms inside the bag, mask, and suction device.

CLEANING: To completely remove debris from the equipment, all surfaces must be scrubbed with a small, soft brush or clean gauze/cloth. This will allow for successful sterilization or HLD. Soaking alone will soften, but not remove debris. Stuck-on debris can protect microorganisms from sterilization or HLD.

RINSING AFTER CLEANING: To prevent soap residue from sticking to the equipment, all equipment must be thoroughly rinsed in clean water. Soap residue will impact sterilization or HLD. Further, any residue left on the equipment could be introduced into the infant’s airway.

AS NEEDED:

► **REMOVAL OF LIMESCALE (calcium carbonate):** Limescale is formed by the build-up of minerals that are found in water. This is a special step performed only as needed. Removal of limescale helps keep the equipment in working order. This process requires the use of white vinegar 3 to 5%.

► **DEPENDING ON DISINFECTION METHOD SELECTED:**

DRYING AFTER CLEANING: To prepare the equipment for chemical HLD or sterilization, equipment must be dried. Any water left on the devices can dilute a chemical disinfectant or may impact the level of drying during autoclaving (also called steam sterilization). Drying is not required before HLD by boiling or steaming (not to be confused with steam sterilization).

3 DISINFECTION STAGE

STERILIZATION OR HIGH LEVEL DISINFECTION: To eliminate all or most microorganisms from equipment surfaces, equipment must be either sterilized or high-level disinfected, depending upon the facility policy and available resources.

► **OPTION 1: STERILIZATION:** Destroys all microorganisms, including bacterial endospores. Steam sterilization requires an autoclave.

► **OPTION 2: HIGH-LEVEL DISINFECTION:** Destroys all microorganisms except for some bacterial endospores. HLD can be achieved by either heat or chemical methods. The four methods of HLD outlined in this guide include:

Heat-based methods:

- Boiling
- Steaming (not to be confused with autoclaving [steam sterilization])

Chemical-based methods:

- Chlorine solution 0.5%
- Activated glutaraldehyde 2.4%

RINSING AFTER CHEMICAL HIGH-LEVEL DISINFECTION: To remove all chemical residue from the equipment after chemical HLD, equipment must be thoroughly rinsed. This step must occur with boiled water. Any remaining chemical residue could dry on the equipment and be introduced into the infant's airway.

DRYING AFTER HIGH-LEVEL DISINFECTION: To avoid growth of new microorganisms, equipment must be fully dried. This step must occur after any method of HLD and before equipment can be inspected, reassembled, tested for functionality, and stored.

4 POST-DISINFECTION STAGE

INSPECTION: To ensure that all equipment parts are intact, each piece must be inspected.

REASSEMBLY: To ensure that equipment is ready for use when resuscitation is required, all components of the equipment must be put together.

FUNCTION TESTING: To ensure that equipment is in working order and has been properly reassembled, equipment must be tested. This step must occur before storing the equipment.

STORAGE: To keep the equipment free of microorganisms and dust until it is needed, equipment must be properly stored.

Appendix 1 outlines the four stages and all reprocessing steps and can be posted in the reprocessing area.

SECTION 2

REPROCESSING MATERIALS AND EQUIPMENT

A variety of materials and equipment are required for reprocessing of basic neonatal resuscitation equipment.

Appendix 2 presents a checklist to indicate what kind of materials are needed for each reprocessing step. The detailed description of each step (**Section 4, Reprocessing Steps**) also contains a reminder of the materials and equipment needed.

In order to accommodate the variety of resources that are available in different facilities, this guide provides several options for certain steps of the process. The necessary equipment for these steps will vary depending upon which process is selected. For example, undertaking HLD by boiling will require different equipment than undertaking HLD with chlorine.

Wearing personal protective equipment (PPE) provides essential protection from the microorganisms found on the equipment and from chemicals that could splash into eyes and onto skin. PPE includes: gloves, cap, mask, eye protection, apron, and footwear. Changing PPE, such as gloves, at certain times during reprocessing and properly removing PPE at the end of reprocessing helps to prevent transmission of microorganisms to other staff, patients, or back on to clean equipment. For more detailed descriptions about PPE, review the [World Health Organization's Practical Guidelines for Infection Control in Health Care Facilities](#).¹⁰

Disposable PPE should be discarded after use following the health facility's policies and guidelines for disposal. Reusable PPE should be cleaned according to the manufacturer's instructions, according to the health facility's policy, or can be cleaned using guidance provided in **Appendix 3**.

SECTION 3

WORKFLOW AND SPACE

Each facility and each unit must consider both their patient volume and available resuscitation equipment to best determine the workflow needed to ensure that there is always sterilized/disinfected equipment ready to be used. Also to ensure that at least the first five steps are consistently performed immediately after equipment use to avoid damage. For example, in busy facilities where there are a number of staff who are responsible for reprocessing, it is advised that a specific person on each shift be tasked with reprocessing on each different day, and that sufficient time in their schedule is specifically allotted to reprocessing. Since the first five reprocessing steps must occur immediately after the equipment is used, it is helpful that in a busy unit there is a designated person that has time to start reprocessing immediately. A monthly roster for each unit within the facility should be determined ahead of time. Whether the appointed reprocessing staff member is a healthcare worker or custodial staff, having designated people each day who are responsible for reprocessing will help staff to become more familiar with reprocessing and with disassembly/reassembly of the resuscitation devices. Also, allotting time specifically for reprocessing will help ensure that equipment is clean and ready for use.

Autoclaves require regular monitoring to ensure they are working properly. In facilities using an autoclave, a specific person should be tasked with the mechanical, biological, and chemical monitoring of the autoclave. **See page 26** for more details on autoclave monitoring.

Reprocessing Space Planning

Setting up the reprocessing space is an important task. A well-designed space will help ensure efficient reprocessing and will help to prevent recontamination of the equipment after it has undergone HLD or sterilization.

Throughout this guide, areas of the reprocessing space are referred to as “dirty” and “clean”. These terms refer to the level of reprocessing that the equipment has undergone up to that point.

- “DIRTY”:** Equipment that is undergoing any part of the process from IMMEDIATE PRE-CLEANING to DRYING AFTER CLEANING. The equipment is still considered to be dirty even if it has been cleaned with soap and water because it has not yet undergone sterilization or HLD and is not ready for use on an infant.
- “CLEAN”:** Equipment that is undergoing STERILIZATION or HIGH-LEVEL DISINFECTION and any of the remaining steps (INSPECTION, REASSEMBLY, FUNCTION TESTING).

General Guidelines for the Reprocessing Space:

1. The “dirty” and “clean” areas of the reprocessing space should be separate. When reprocessing medical equipment, the reprocessing traffic in the room should flow from “dirty” to “clean” in the order of the reprocessing steps. However, when cleaning the reprocessing space, work backwards from “clean” to “dirty” in order to prevent transmission of microorganisms from the “dirty” area into the “clean” area.
2. The ideal situation for reprocessing would be to have separate rooms for “dirty” and “clean” areas.¹² However, if this is not possible, the reprocessing room or area must be separated into “dirty” and “clean” spaces. The area where items undergo sterilization or HLD should be well separated from the dirty equipment area. The addition of a separate table, covered in plastic sheeting (which can be easily wiped), for the “clean” steps of reprocessing could be useful when a separate room is not possible.
3. Reprocessing traffic should flow around the room in one direction from “dirty” to “clean.” See **Figure 1**.
4. The reprocessing space should be kept free of dust and debris. It is advisable to dust and clean the reprocessing space every morning in preparation for the day.
5. The reprocessing space must be indoors (to avoid dust and debris) and care should be taken that the solutions are not in direct sunlight at any time of the day because it will decrease their effectiveness.
6. The reprocessing area should be separate from the patient care and public areas of the unit or facility.
7. Reprocessing buckets should be easily reachable to prevent the need for repeated crouching or bending, which puts workers at increased risk for fatigue, musculoskeletal disorders,¹³ and poor blood circulation.¹⁴ Ideally, the buckets should be placed above the floor level in a position that is comfortable for the staff.
8. Reprocessing materials/equipment should be kept in the reprocessing space to facilitate reprocessing.
9. Chemicals:
 - Proper ventilation is important when using chemicals.
 - Chemicals must be stored in a manner that is safe. See **Appendix 4** for proper chemical care and storage.
 - Chemicals must be disposed of following local guidelines.

The reprocessing space in every facility will vary in dimensions and in access to nearby water. When setting up the reprocessing space, the checklist on **page 7** identifies issues that should be considered when arranging a reprocessing area. See **Figure 2** for an example layout of the reprocessing space.

Checklist for Setting up the Reprocessing Space

- ☐ Identify where “dirty” area and “clean” area begin and end.
- ☐ Identify surfaces (tables, cabinets) needed for each area.
- ☐ Identify where clean gloves and clean PPE will be kept.
- ☐ Identify where buckets, soap, chemicals, and clean gauze/cloth will be stored and easily available.
- ☐ Identify where prepared buckets with solutions and clean water will be placed (“dirty” and “clean” areas).
- ☐ Identify the water source. If water is not clear, identify where filtering of water will be done.
- ☐ Identify the surface where dirty equipment will be placed immediately before reprocessing begins.
- ☐ Identify areas where equipment will undergo each step. Keep in mind that the traffic pattern should move from dirty equipment to sterilized/high-level disinfected.
 - ☐ IMMEDIATE PRE-CLEANING
 - ☐ DISASSEMBLY
 - ☐ CLEANING
 - ☐ RINSING AFTER CLEANING
 - ☐ DRYING AFTER CLEANING (when appropriate)
 - ☐ STERILIZATION **OR** HIGH LEVEL DISINFECTION
 - ▶ If using an autoclave that is located outside the unit, determine process for equipment to reach that area.
 - ▶ If using a boiling apparatus or steamer, identify where equipment will be kept.
 - ☐ RINSING AFTER CHEMICAL HLD
 - ☐ DRYING AFTER HLD
- ☐ Identify clean space where equipment that has undergone sterilization/HLD will be placed for inspection, reassembly, and function testing.
- ☐ Identify where logs will be placed (HLD log, glutaraldehyde monitoring log, autoclave monitoring log, as appropriate).
- ☐ Identify where fully reprocessed equipment will be stored.
- ☐ Identify where non-working devices will be placed until they have been checked by a supervisor. This area must be away from the patient treatment area, so that non-functional equipment will not be confused with functional equipment.
- ☐ If a device has been determined to be non-functional, some parts may be useful for repairing other resuscitators of the same brand and model. Identify where these spare parts will be stored.
- ☐ Identify where broken components will be stored/discarded (will depend upon facility protocol for non-functional equipment).

Figure 1. Reprocessing space layout.

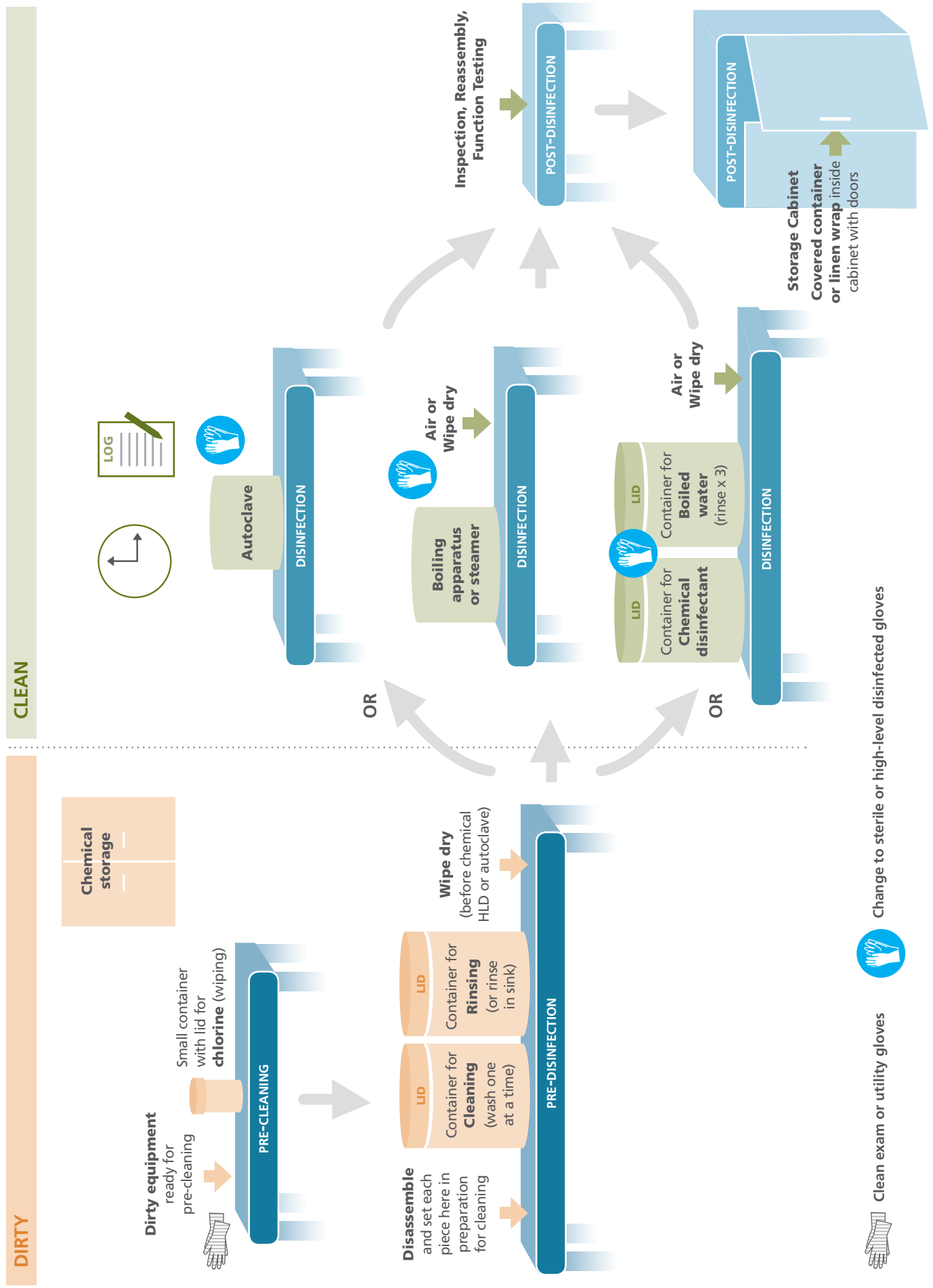


Figure 2. Example of a reprocessing space that uses chemical high-level disinfection. In this example, the space is organized from right to left according to the preference of the facility staff, but space may also be organized from left to right.

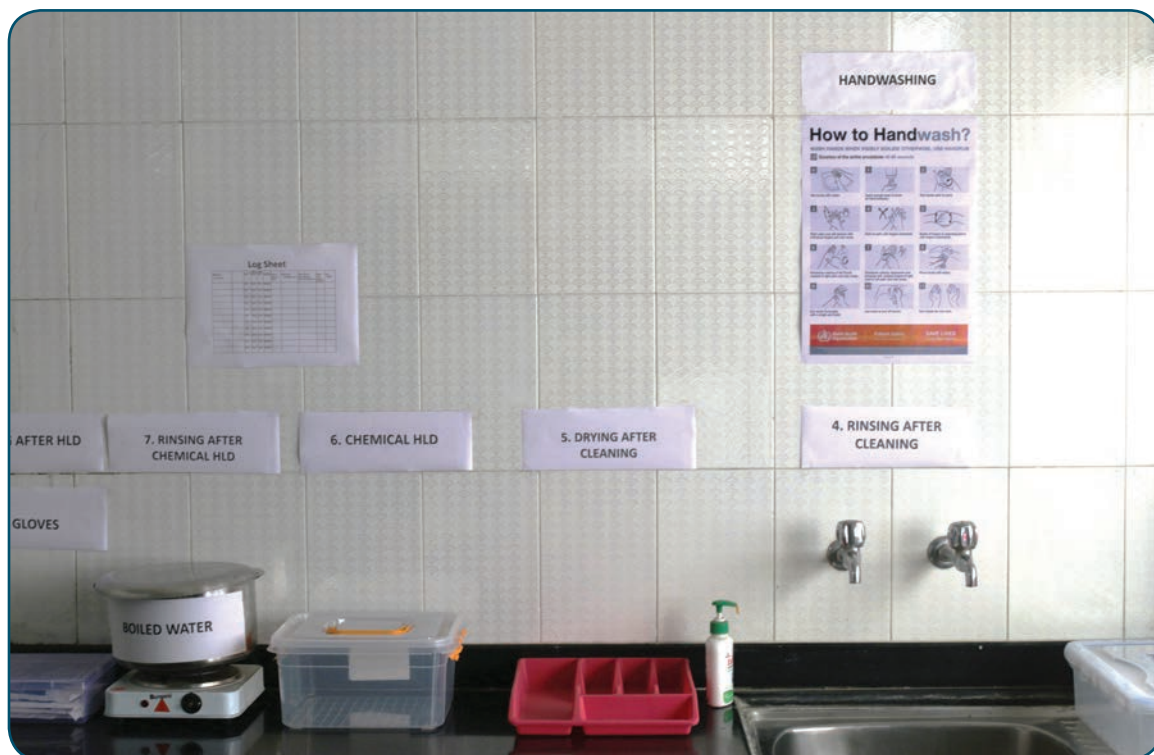


Overview of entire reprocessing space.

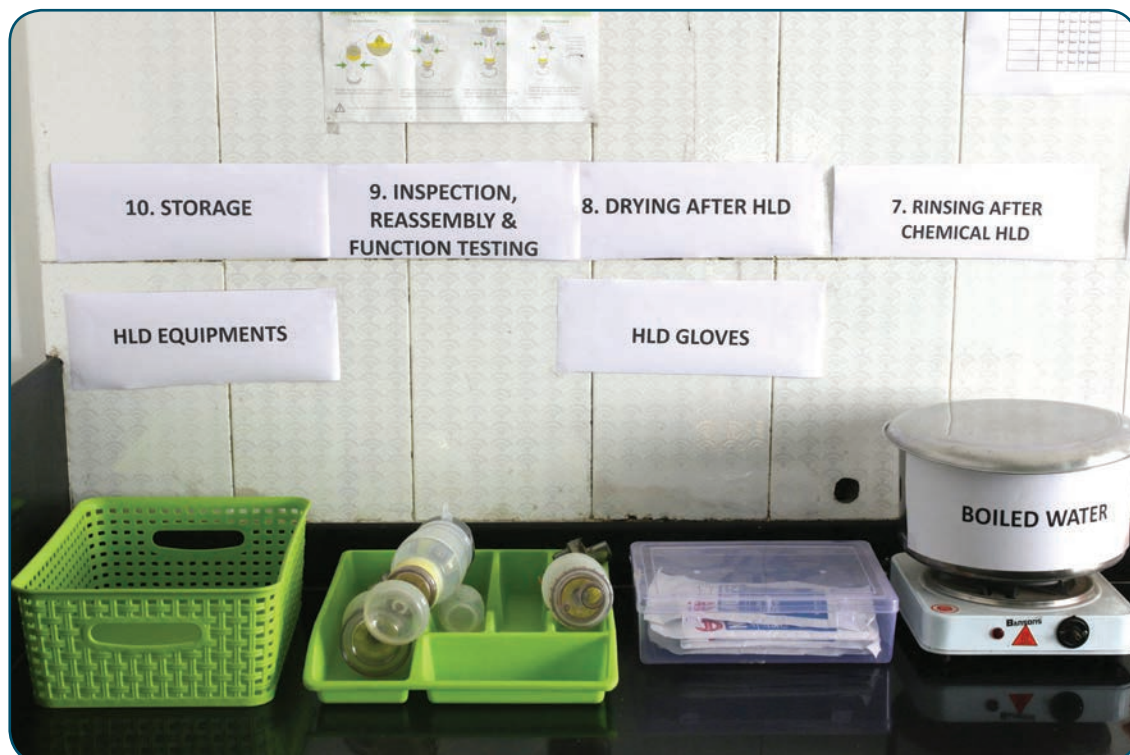


IMMEDIATE PRE-CLEANING to CLEANING

Close up of IMMEDIATE PRE-CLEANING and DISASSEMBLY



RINSING AFTER CLEANING to CHEMICAL HIGH-LEVEL DISINFECTION



RINSING AFTER CHEMICAL HIGH-LEVEL DISINFECTION to STORAGE

SECTION 4

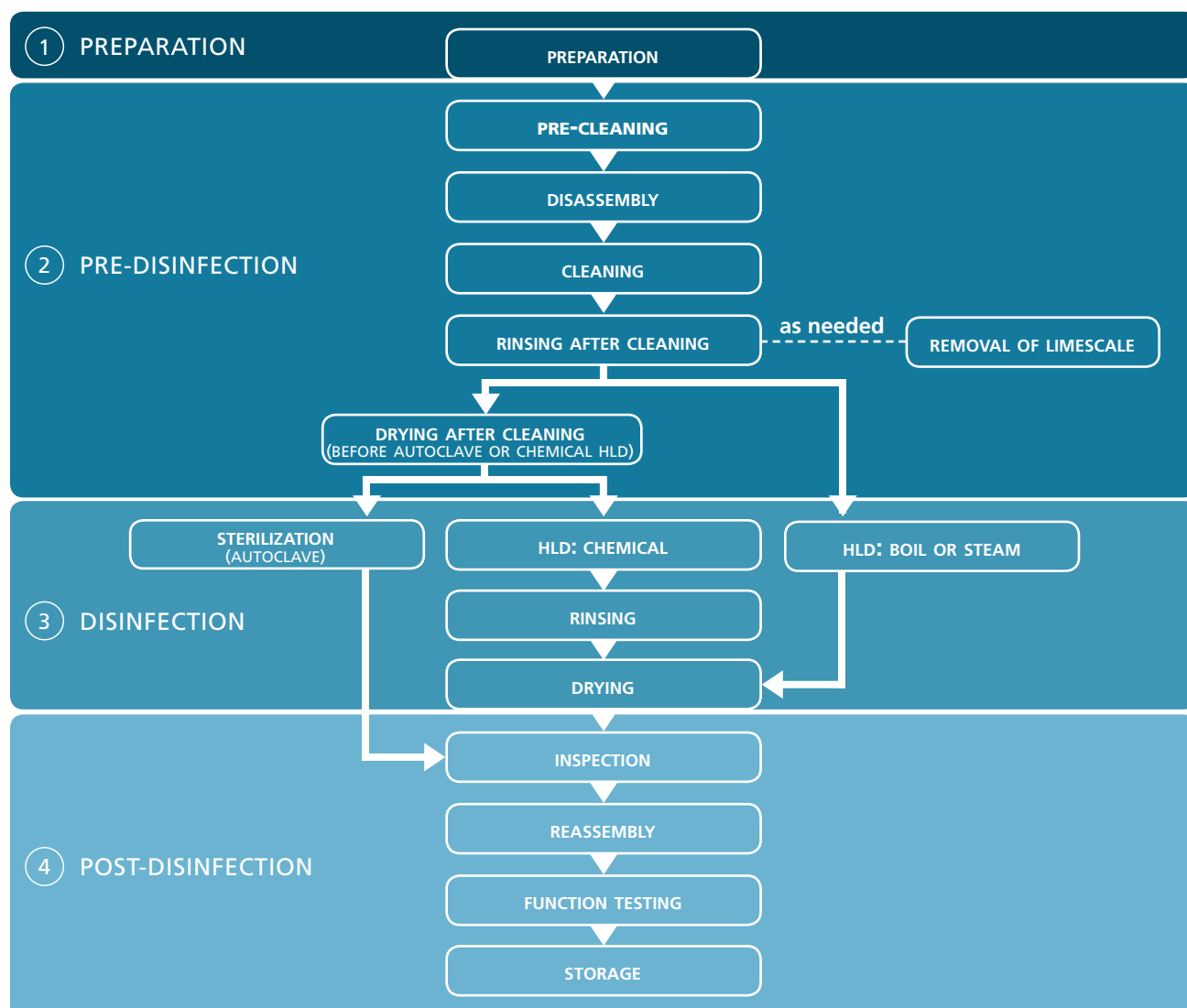
REPROCESSING STEPS

As described earlier, there are four main stages involved in reprocessing basic neonatal resuscitation equipment: PREPARATION, PRE-DISINFECTION, DISINFECTION, and POST-DISINFECTION. Each stage involves one or more reprocessing steps. The stages and steps to follow are outlined in **Figure 3** below (also found in **Appendix 1**).

How to Use the Job Aids:

Job aids and other resources were developed to be posted in the reprocessing area to aid during the reprocessing procedure. The general job aid can be found at <http://www.path.org/publications/detail.php?i=2601>, and additional resources can be found in the appendices of this guide. The general job aid provides an overview of the Preparation Stage, Pre-Disinfection Stage, Disinfection Stage, and the Post-Disinfection Stage. If using HLD rather than sterilization, select the best HLD method for the facility and print the corresponding appendix for that method (**Appendices 10 through 13**). Post the selected page next to the general job aid in the reprocessing area.

Figure 3. Outline of reprocessing stages and steps.



HLD = High-level disinfection

Before beginning reprocessing, a note about gloves:

DO:

- Begin reprocessing with a pair of clean utility or exam gloves.
- Change to sterile or high-level disinfected gloves once equipment has been sterilized or disinfected.
- Remove gloves if it is necessary to leave the reprocessing area or undertake any other tasks.

DO NOT:

- Wear gloves that were used during patient care as this will introduce further bacteria to the reprocessing environment.
- Wear torn or punctured gloves.

Best practice is to put on a new pair of gloves between each reprocessing step. However, this may not be realistic in resource-limited settings. If new gloves are not possible for each step, wear the same gloves only for certain steps as outlined in **Figure 4**.

Figure 4. Use of gloves in different reprocessing steps if new gloves cannot be used for each step.

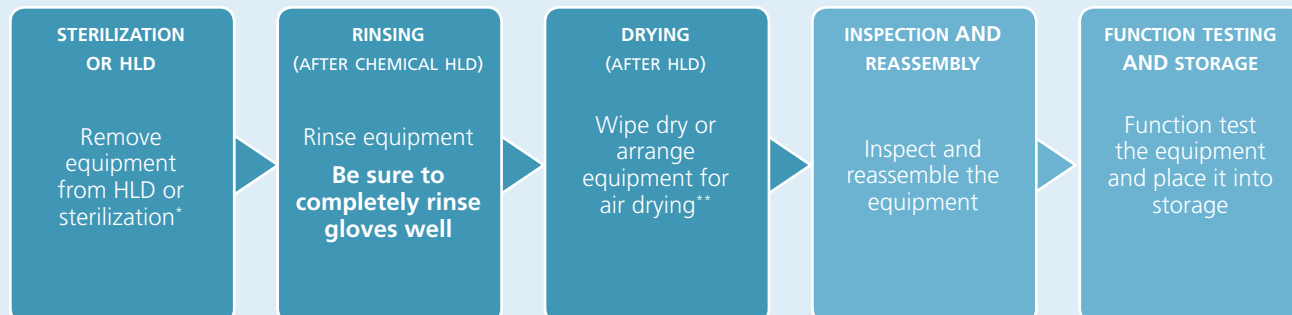
USING THE SAME CLEAN EXAM OR UTILITY GLOVES DURING “DIRTY” STEPS.

Start with clean exam or utility gloves, then follow these steps:



USING THE SAME NEW STERILIZED OR HIGH-LEVEL DISINFECTED GLOVES DURING “CLEAN” STEPS.

Start with sterile or high-level disinfected gloves, then follow these steps:



* Use sterile or high-level disinfected gloves or use high-level disinfected forceps (instead of gloves) to remove equipment from container or machine. However, sterilized or high-level disinfected gloves must be worn to handle equipment during the next step.

** If air drying equipment, a new pair of gloves will be needed when returning to complete the next reprocessing steps (Inspection, Reassembly, Function Testing, Storage) because the gloves used before will be contaminated by this time.

1 PREPARATION STAGE

The PREPARATION step is the first step in the reprocessing of neonatal resuscitation devices. Its purpose is to ensure that the reprocessing area and reprocessing materials and equipment are able to be used immediately after the resuscitation equipment has been utilized. This requires preparing everything before patient care begins. Reprocessing equipment immediately after use will prevent microorganisms from drying on and sticking to the equipment and it will also help prevent transmission of microorganisms from the patient area into the reprocessing area.

Wear complete PPE when preparing or using chemicals to avoid injuries and risk of contamination. Complete PPE includes clean exam or utility gloves, cap, mask, eye protection, apron, and boots.

General Guidance

- Prepare the reprocessing area each day so that it is ready for use. It is essential to use clean exam or utility gloves when preparing the reprocessing area. Undertaking this activity before engaging in patient care will help prevent the transmission of microorganisms from patient care onto reprocessing equipment/materials.
- Ensure that the general job aid for reprocessing is available and posted in the reprocessing area.
- At the beginning of each shift, identify how many resuscitation devices are available for use. A device is “available for use” if the device has been completely reprocessed, inspected, reassembled, and tested. Devices that are not working properly should be removed from the patient treatment area.
- Know where the sterilization/HLD logs are located. Use of these logs will help health care facility staff understand when each process last occurred during the previous shift.

Cleaning the Reprocessing Area

- The reprocessing area should be cleaned each day.
 - Prepare chlorine solution 0.5% in a small plastic container for wiping surfaces in the reprocessing space.
 - Remove any debris from the area.
 - Wipe all surfaces, including counters/tables/carts/buckets with a clean cloth soaked in chlorine solution 0.5%. Begin with the “clean” areas and then proceed to the “dirty” areas to prevent transmission of microorganisms around the reprocessing areas (for a definition of “clean” and “dirty” areas, please see **page 5**).
 - Mop the floor with chlorine solution 0.5% (or with the appropriate disinfectant used in the facility for mopping). Mopping solution should not be reused for any other purpose.
- Ensure that the chosen method of sterilization or HLD is ready for use.

Preparing the Reprocessing Space for Use

As described in the section on Reprocessing Space Planning (see **page 5**), the reprocessing area should have a space for “dirty” equipment and a space for “clean” equipment.

PREPARATION STAGE (CONTINUED)

Preparing the Reprocessing Materials

Whenever basic neonatal resuscitation equipment is reprocessed, several containers or pieces of equipment must be prepared. These include a chlorine solution 0.5% for IMMEDIATE PRE-CLEANING, soapy water for CLEANING the equipment, and clean water for RINSING. Depending upon the method of sterilization or HLD used at the facility, prepare the autoclave, boiling container/machine, steamer, or the chemical disinfectant and boiled rinse water.

Considering number of deliveries or number of beds in the special newborn care unit, the unit staff needs to decide the best time to prepare the containers of chlorine solution 0.5%, soapy water, clean water, and/or other chemical disinfectants, as well as boiled water.

- If there are deliveries/unstable newborns **each day**, then prepare the containers first thing in the morning.
- If there are only a few deliveries/unstable newborns **each week**, then it may make most sense to prepare these containers just before a delivery so that supplies are not wasted.
- **Prepare the reprocessing space and materials with clean exam or utility gloves. Never use dirty gloves to prepare the reprocessing area or reprocessing equipment. Use of clean gloves will prevent transmission of microorganisms throughout the reprocessing area.**
- **Chlorine degrades quickly. Prepare new containers of chlorine solution every 24 hours or when the solution becomes cloudy (whichever occurs first). The dilution instructions for chlorine solutions are found in Appendices 5 and 6 (for posting in reprocessing area).**
- **Use soapy water solution only once (i.e., after cleaning a batch of resuscitation equipment). Prepare a new container of soapy water each time reprocessing is performed in order to prevent the use of dirty water to clean other equipment.**
- **Change rinse water (whether clean or boiled, depending on the step) after it has been used once to ensure adequate rinsing of soap and chemical disinfectants from all items.**
- **All containers must be plastic. Cover containers with well-fitting lids while not in use.**
- **Label all containers with their contents and the date and time of preparation (use masking tape and permanent markers).**

Large loads of microorganisms and organic debris will quickly make solutions ineffective. Moreover, metal equipment can give off rust that can discolor silicone equipment (**Figure 5**). For this reason, do not mix equipment when reprocessing. Reprocess resuscitation equipment by itself and not with delivery equipment or any other equipment in the same solutions at the same time.



Figure 5: A penguin suction device that was boiled with metal instruments. Photo credit: PATH/Manjari Quintanar Solares

Clean Water Preparation Instructions

If the reprocessing area has a sink with running clean and clear water, use it to prepare chlorine solutions and for the RINSING AFTER CLEANING step. If water is not clear (has some type of debris floating in it), then filter the water before use. Most debris can be removed by filtering through four layers of moderately woven cotton cloth, such as cheese cloth or old sari material.¹²

If there is no sink with running clean and clear water, then fill a large plastic container (10 to 20 L bucket) with clean water. Filter water if necessary as described above. The container should be large enough to fully immerse the largest piece of equipment that will be cleaned. Once prepared, cover the container and label it with the name of the contents ("Clean Water") and the date and time it was prepared.

Boiled Water Preparation Instructions

When using chemical HLD, boiled water will be needed to rinse the equipment after disinfection has taken place. Only boiled water should be used to maintain the level of disinfection achieved through the chemical HLD process. If the water is not clear, filter it before boiling. Boil enough water to fill three large plastic containers (10 to 20 L buckets). Boil the water for 20 minutes and let it cool. Once prepared, cover the container and label it with the name of the contents ("Boiled Water") and the date and time it was prepared.

Chlorine Dilution Instructions

Chlorine is a common disinfectant found in health facilities all over the world. There are several instances during reprocessing of neonatal resuscitation equipment where a chlorine solution can be used. These include:

- Preparing the reprocessing area (disinfection of surfaces and floors).
- Pre-cleaning the resuscitation equipment immediately after use (this helps protect health care facility staff from microorganisms that are on the devices).
- HLD of the resuscitation equipment (this helps protect an infant from microorganisms that could still be on the device after cleaning with soap and water). In order for chlorine to be effective as a disinfectant, the equipment must have been thoroughly cleaned with soapy water and scrubbed, as organic matter on the equipment may inactivate the chlorine.

There are several types of chlorine that may be available in the health facility:

FORM	NAME	CHEMICAL FORMULA
Liquid	Sodium hypochlorite (known as household bleach)	NaClO
Powder or Tablet	Calcium hypochlorite (powder)	Ca(ClO) ₂
	Chloramine (tablets)	NH ₂ Cl
	Sodium dichloroisocyanurate (tablets)	NaDCC

The most commonly available chlorine products used for reprocessing of medical equipment are sodium hypochlorite liquid and calcium hypochlorite powder. Chloramine and sodium dichloroisocyanurate are more commonly used for water treatment.

PREPARATION STAGE (CONTINUED)

Important Chlorine Dilution Information

For **all** uses of chlorine described in **this guide**, the **final strength after dilution is a 0.5% solution**.^{12,15,16} A 0.5% solution is important because it is of sufficient strength to function as a high-level disinfectant. The cleanest possible water that is available should always be used when preparing a chlorine solution as organic matter in the water can decrease the effectiveness of the chlorine. In some cases, filtering may be necessary if water is cloudy or filled with particles.

Chlorine products contain different amounts of available chlorine, even within the same brand name (see **Figures 6 and 7**). The amount of available chlorine will directly affect how much water is added to the product to achieve a 0.5% solution. It is very important to check the amount of available chlorine in the product that will be used. For example, the available chlorine in sodium hypochlorite can range from 2.4% to 15%, while the available chlorine in calcium hypochlorite powder is often 35% or 70%.

- **Always wear appropriate PPE when handling chemicals.**
- **Do not use expired chemicals.**
- **Use only room temperature water to dilute chlorine. Higher temperatures impact the efficacy of chlorine disinfection.**
- **Use only plastic (never metal) containers to prepare the chlorine solution to avoid rusting and/or other chemical interactions.**^{17,18}
- **Do not mix chlorine with soap or any other chemical due to the potential for hazardous fumes.**
- **Chlorine degrades quickly, so a new container of chlorine must be prepared every 24 hours or when the solution becomes cloudy (whichever occurs first).**¹⁷

Prepare sufficient chlorine solution 0.5% to have enough for all the reprocessing needs. Before use, divide the solution into separate containers so that no cross-contamination occurs during use. For example, if chlorine solution will be used for the HIGH-LEVEL DISINFECTION step, prepare several liters of the chlorine solution in a large container. Pour some solution into a smaller container (approximately 1 L) to use for IMMEDIATE PRE-CLEANING and also to pour some into a bucket to use for cleaning the reprocessing space. There must be enough chlorine solution 0.5% left in the large container to fully submerge the equipment during HIGH-LEVEL DISINFECTION.

Dilution for liquid bleach (sodium hypochlorite) to create a 0.5% solution.¹²

Detailed dilution instructions are found in **Appendix 5**. The appendix can be removed from the guide or photocopied and posted in the reprocessing area of the health facility to serve as a job aid.

Dilution for dry bleach powder/tablets to create a 0.5% solution.¹²

The dilution instructions are found in **Appendix 6**. The appendix can be removed from the guide or photocopied and posted in the reprocessing area of the health facility.



Figure 6. Examples of how available chlorine information is displayed on household bleach bottles.

Photo Credits: PATH/Manjari Quintanar Solares

These two bottles of household bleach are from the same manufacturer, are sold under the same brand name, and are both available in the same country. However, they contain different amounts of available chlorine. The bottle on the left contains 3.85% available chlorine, while the bottle on the right contains 6% available chlorine. Different amounts of water are required to dilute each of these products to achieve a 0.5% solution.

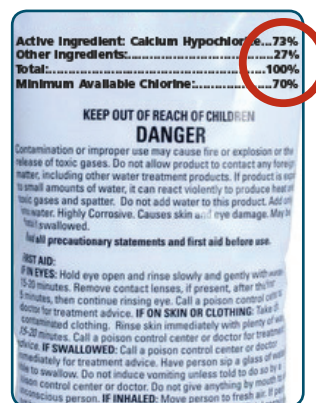


Figure 7. Example of how available chlorine information might be displayed on a dry bleach powder container.

Soapy Water Preparation Instructions

In a large plastic container (10 to 20 L bucket), mix mild, liquid soap with clean water. The container should be large enough to fully immerse the largest piece of equipment that will be cleaned.

There is no specific liquid soap-to-water ratio recommended, but put enough liquid soap to generate bubbles and for the solution to have a slippery consistency. Use liquid soap like the type used for handwashing dishes. If the facility has an enzymatic cleaner, it should be used in accordance with manufacturer's instructions. Powdered detergents are not recommended because they do not mix as well with water and do not remove oil and grease as well as liquid soap. Bar soap is not recommended because it leaves a residue when used with hard water. Once prepared, cover the container and label it with the name of the solution ("Soapy Water") and the date and time it was prepared.

2 PRE-DISINFECTION STAGE

A IMMEDIATE PRE-CLEANING

It is important to reprocess equipment immediately after use.

NOTE: in some reprocessing guidelines, the term “decontamination” is used to refer to this step. However, it has been observed that the term “decontamination” is easily confused with “high-level disinfection”, which is a separate process. Therefore, the term “immediate pre-cleaning” is used to reduce confusion between this step and the disinfection step.

IMMEDIATE PRE-CLEANING makes medical equipment safer to be handled by staff before cleaning. **The intention of immediate pre-cleaning is to protect health care facility staff by removing and partially inactivating viruses such as HBV, HCV, and HIV.** This process reduces, but does not eliminate, the number of other contaminating microorganisms.¹² Further cleaning and sterilization or disinfection must occur before the equipment is safe for use on an infant. Immediate pre-cleaning also prevents microorganisms and other organic matter from soaking into the silicone.

Materials and Equipment

- Chlorine solution 0.5%
- Small plastic container (approximately 1L, with a tight-fitting lid)
- Clean gauze/cloth
- PPE
 - Clean exam or utility gloves
 - Cap
 - Mask
 - Eye protection
 - Apron
 - Protective boots

IMMEDIATE PRE-CLEANING should occur before any disassembly of the equipment.

Instructions:

STEP 1: Put on PPE, including clean exam or utility gloves.

STEP 2: Check the label of the container to confirm correct solution (chlorine solution 0.5%) and the date/time the solution was prepared to ensure the solution is less than 24 hours old.

STEP 3: Dip a new piece of clean gauze/cloth into the small plastic container of chlorine solution 0.5% that was prepared in the PREPARATION step.

STEP 4: Wipe the outside of the fully-assembled ventilator bag and mask, the inside of the mask, and the outside of the suction device with the chlorine soaked gauze/cloth. Re-soak the gauze/cloth each time a different piece of the equipment is wiped. If the equipment is visibly covered in blood or other bodily fluids, it is recommended to use a new piece of gauze to wipe each piece of the equipment.

The chlorine solution used for this step should be kept in a small container (approximately 1 L) with a tight-fitting lid while it is not being used. If also using a chlorine solution for the HIGH-LEVEL DISINFECTION step, keep the two chlorine solutions separate. This will prevent the HLD chlorine solution from becoming contaminated with debris from the IMMEDIATE PRE-CLEANING step which could inactivate the chlorine.

Special Information:

- The chlorine solution should be changed daily or when it becomes cloudy, whichever occurs first.
- Never leave gauze soaking in the chlorine solution. Follow health facility policy to dispose of the gauze after use.
- Do not use cotton wool in any reprocessing step as fibers from the cotton can interfere with the efficacy of the sterilization or disinfection steps.
- Enzymatic detergent is not a disinfectant and should not be used as such.¹¹

B

DISASSEMBLY

DISASSEMBLY ensures that all internal and external surfaces of the devices can be thoroughly cleaned and that the sterilization or HLD method reaches all surfaces. Microorganisms can reach every area of the bag, mask, and suction device even if they appear to be clean.

Instructions:

STEP 1: Wear the same gloves that were used for IMMEDIATE PRE-CLEANING.

STEP 2: Completely disassemble the equipment and place each piece on a dry surface in preparation for cleaning.

STEP 3: When disassembling equipment with multiple components, such as the ventilation bag, count the number of pieces to ensure that there are the same number of pieces at REASSEMBLY.

Review the manufacturer's instructions for tips on how to disassemble the ventilation bag.

STEP 4: Open the suction device, pointing away to avoid splashing any mucus or other bodily fluids on face.

PRE-DISINFECTION STAGE (CONTINUED)

C CLEANING

CLEANING removes debris that is stuck on the equipment and further reduces the number of microorganisms on the device.

Neither sterilization nor HLD will be effective unless the device has been properly cleaned first.^{10,11,12}

Instructions:

STEP 1: Wear the same gloves used for IMMEDIATE PRE-CLEANING and DISASSEMBLY.

STEP 2: Use the large container of soapy water that was prepared in the PREPARATION step to **wash gloved hands in the soapy water.**

STEP 3: Wash one piece of the equipment at a time in the soapy water by scrubbing each piece of equipment using a piece of clean cloth or clean gauze (do not use the same gauze used during IMMEDIATE PRE-CLEANING). Scrubbing creates friction which is necessary to remove any organic debris that is stuck on the equipment.

STEP 4: Scrub all surfaces of the equipment, both inside and outside. A small soft brush or a narrowly rolled gauze can help reach all the surfaces.

STEP 5: After cleaning each piece, drop it into the bucket of clean rinse water.

STEP 6: The reusable suction device must be opened and the inside should be scrubbed. A toothpick is a useful tool to clear all mucus/bodily fluids out of the tip of the suction device. Single-use suction bulbs should be discarded after use as they cannot be opened for cleaning.

Materials and Equipment

- Soapy water (prepared with mild liquid soap like the type used for washing dishes).
- Large plastic container (10 to 20 L bucket, with tight-fitting lid)
- Small, soft brush (such as a toothbrush)
- New, clean gauze/cloth
- Toothpick
- PPE
 - Clean exam or utility gloves
 - Cap
 - Mask
 - Eye protection
 - Apron
 - Protective boots

Special Information:

- Soapy water should be changed after using it once (i.e., after cleaning a batch of resuscitation equipment) to avoid cleaning other equipment with dirty water.
- Do not allow equipment to soak in the water too long as this can impact the lifespan of the equipment.
- Do not use cotton wool for scrubbing. Fibers from cotton wool can stick to the device and can interfere with sterilization or disinfection.
- Do not mix chlorine with soap due to the potential for hazardous fumes.
- If using an enzymatic cleaner, be aware that it is not a disinfectant and should be treated as such.¹¹ Examples of enzymatic cleaners include Endozime® Bio-Clean and Enzol®.
- Do not use abrasive cleaners as they can damage the equipment.

D RINSING AFTER CLEANING

RINSING AFTER CLEANING is necessary to remove any detergent residue on the equipment. Residue that remains on the equipment could interfere with sterilization or disinfection.¹¹

Instructions:

STEP 1: Wear the same gloves used during CLEANING step.

STEP 2: Use the large container of clean water prepared in the PREPARATION step to **rinse gloved hands** or rinse them under clean, running water, if available.

STEP 3: Rinse the equipment. If clean, running water is available in the reprocessing area, rinse the equipment under the running water. If running water is not available, completely immerse the equipment in the container of clean water. Move the equipment around in the clean water until no more detergent residue is visible on the equipment.

If there is no access to a sink with running water, the clean rinse water needs to be changed after it has been used once to ensure adequate rinsing of soap from the equipment. As soap builds up in the water, with repeated use, it will no longer adequately remove residue from the equipment.

If available, use hot water for rinsing equipment as hot water removes soap residue more quickly.¹⁰ However, if hot water is not available, use room-temperature water.

STEP 4: After rinsing thoroughly, set each piece of equipment in the area assigned for drying.

Materials and Equipment

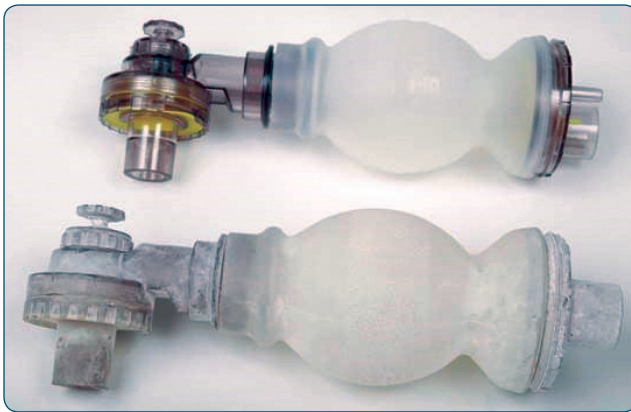
- Sink with clean, running water
- OR**
- Large plastic container (10 to 20 L bucket, with tight-fitting lid) with clean water
- PPE
 - Clean exam or utility gloves
 - Cap
 - Mask
 - Eye protection
 - Apron
 - Protective boots

PRE-DISINFECTION STAGE (CONTINUED)

► SPECIAL STEP REMOVAL OF LIMESCALE (CALCIUM CARBONATE)

**This step should only be performed
AS NEEDED.**

Limescale (or calcium carbonate) is a white, chalky build-up caused by hard water (water with a high mineral content) and it is common throughout the world. Reprocessing equipment using hard water can cause limescale to form on the equipment, but it is easily removed with a solution made from water and white vinegar. This step is not a routine part of neonatal resuscitation equipment reprocessing and should only be done when the equipment becomes cloudy or coated with mineral deposits (**see Figure 8**). This step should occur **after** cleaning and rinsing the equipment, but **before** drying and sterilization



Materials and Equipment

- Household white vinegar (3 to 5% concentration recommended)
- Clean water
- Large plastic containers (10 to 20 L, should be able to fully immerse the largest piece of equipment). Only plastic containers should be used as vinegar will corrode metal.
 - One container for vinegar solution
 - One container for rinsing if running water is not available nearby
- Clock/watch
- PPE
 - Clean exam or utility gloves
 - Cap
 - Mask
 - Eye protection
 - Apron
 - Protective boots

Figure 8. Clean equipment (top) and equipment covered with limescale (bottom).

Photo credit: Laerdal Global Health

Instructions:¹⁹

STEP 1: After cleaning and rinsing the equipment, and wearing the same gloves, immerse all parts in a bucket of **equal parts** water and household white vinegar (3 to 5% concentration recommended). Ensure that all parts of the equipment are filled with the solution so that they do not float.

STEP 2: Leave immersed in the solution for 10 minutes.

STEP 3: After 10 minutes, remove parts from the solution.

STEP 4: Rinse in clean running water or by immersing parts completely in a container of clean water until the components no longer smell of vinegar. If immersing equipment in a container of water, move the equipment around in the water to facilitate the removal of any vinegar residue.

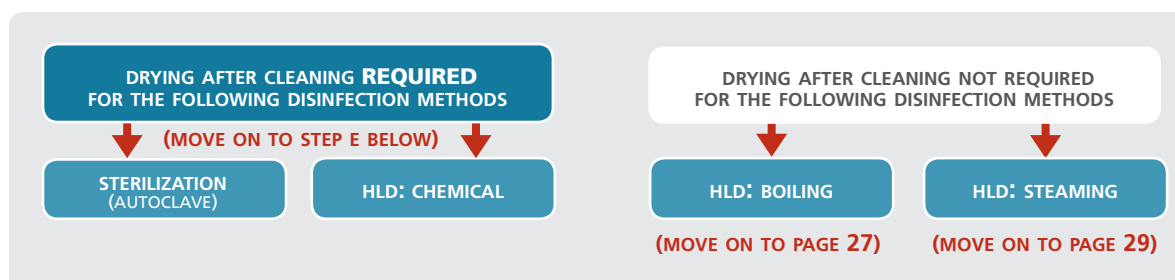
STEP 5: If limescale is not sufficiently removed, repeat the vinegar treatment and rinsing until all parts appear completely clean from surface coating.

STEP 6: Proceed to sterilization or HLD of the equipment. Be sure to dry the equipment before sterilization or chemical HLD (see next step).

In areas where limescale is a constant problem, using cleanly collected rain water for reprocessing may help to prevent limescale build-up.

Before moving on to the next step:

In some cases, it is necessary to dry the equipment before sterilization or HLD. Using the diagram below, determine whether or not the equipment should be dried at this stage based upon the method of sterilization or HLD that will be used next.



E DRYING AFTER CLEANING

DRYING AFTER CLEANING is only needed before sterilization or chemical HLD. Any water left on the devices can dilute a chemical disinfectant or impact the level of drying during the autoclaving (also called steam sterilization) process. Drying does **not** need to occur before boiling or steaming (not to be confused with steam sterilization).

Instructions:

STEP 1: Wear the same gloves used in the previous step.

STEP 2: Take clean gauze/cloth and dry the inside and outside of each piece of equipment as best as possible.

STEP 3: Set equipment in a clean area in preparation for HLD or sterilization.

Materials and Equipment

- Clean cloth or gauze
- PPE
 - Clean exam or utility gloves
 - Cap
 - Mask
 - Eye protection
 - Apron
 - Protective boots

3 DISINFECTION STAGE

Sterilization or HLD is a crucial step for neonatal resuscitation equipment to prepare it for use on the next infant who needs resuscitation. Although sterilization is the most effective method for preparing medical equipment for patient use, the resources for sterilization do not exist in all settings. In such a case, HLD is the minimum requirement for preparing neonatal resuscitation bags, masks, and suction devices for patient use.

The best method of disinfection for a facility will depend on two factors:

1. The manufacturers' instructions for existing equipment. These instructions are related to the material equipment is made of and the methods that have been validated by the manufacturer.
2. The reprocessing resources (materials and equipment) that are available at the facility.

On some occasions, manufacturers' instructions may not be available in the unit, and the staff responsible for reprocessing must determine as best as possible which disinfection methods can be used for the existing reusable equipment. One way is to look for any text imprinted into the equipment. For example, certain reusable resuscitators may state "autoclavable" or "silicone". In those cases, it is likely safe to assume that such equipment can be disinfected through any of the disinfection methods described in this guide. In some facilities, single-use equipment may still be found in the facility. Single-use equipment should be discarded after one use and not be reused. It was not designed to be disassembled or to withstand disinfection methods. Reusing single-use equipment poses an infection risk to babies. One way to identify single-use equipment is by looking for text imprinted onto the equipment such as "single-use" or "②".

A1 STERILIZATION

Sterilization¹² is the preferred method to make resuscitation equipment ready for reuse because it destroys all microorganisms, including bacterial endospores. High-pressure steam sterilization (autoclaving) is an effective method of sterilizing neonatal resuscitation equipment. Dry heat methods of sterilization should never be used for resuscitation equipment (only metal and glass can safely undergo dry heat sterilization). It is essential that equipment be thoroughly cleaned and dried before sterilization. Some debris, such as greasy substances, can protect microorganisms from the effects of the steam, thereby preventing sterilization.

When using an autoclave (steam sterilizer) for resuscitation equipment, follow the manufacturer's instructions for optimal functionality. Some general instructions are included below.

Because resuscitation equipment needs to be reassembled after sterilization, it may be sterilized without wrapping it as long as components from the same resuscitator can be kept together in the same tray or drum/container. If certain small components, such as membranes and valves, cannot be guaranteed to be kept with their specific ventilation bag, then items should be wrapped together to avoid errors during reassembly. When wrapping items, it is best to wrap clean instruments or

Materials and Equipment

- Electric sterilizer + power source
 - Alternative: non-electric sterilizer + kerosene or other fuel
- Sterilization log
- Timer/clock/watch
- Wrap (if necessary)
 - Muslin or other porous material (example: newsprint/paper)
 - Linen ties or masking tape to secure packs
- PPE
 - Clean exam or utility gloves (for loading the sterilizer)
 - Sterile or high-level disinfected gloves (for handling equipment after sterilization is completed)
 - Cap
 - Mask
 - Eye protection (from steam)
 - Apron

other clean items in a double thickness of clean muslin or newsprint/paper. Instruments should not be held too tightly together by rubber bands or any other means because that will prevent steam contact with all surfaces.

Instructions:

STEP 1: Wear the same gloves used during the CLEANING step.

STEP 2: Place unwrapped components on a tray with enough room to allow free circulation of the steam.

STEP 3: If equipment is wrapped, arrange packs in the chamber to allow free circulation and penetration of steam to all surfaces.

STEP 4: Determine the correct temperature and time needed to sterilize the equipment in the type of autoclave available. Temperatures for steam sterilization range from 121°C to 132°C. Refer to the resuscitation device manufacturers' instructions to determine at which temperature the device can be sterilized. Be aware that higher temperatures shorten the equipment's lifespan, and lower quality equipment may not be able to withstand higher temperatures. If the manufacturers' instructions are not available, use the tables in **Appendix 7** to determine the temperature and time recommended. Keep a record of the sterilization process using the sterilization log provided in **Appendix 8**.

If using a pressure cooker or kerosene-powered (nonelectric) gravity displacement steam sterilizer, bring the water to a boil and let steam escape from the pressure valve; then turn down heat, but only to the extent that will keep some steam coming out of the pressure valve.

STEP 5: Once the complete sterilization cycle is done, let equipment cool before removing it from the autoclave. **Wear a mask to avoid contaminating the sterile equipment. Use sterile forceps or high-level disinfected gloves to remove equipment from the autoclave** in order to maintain its sterile status.

STERILIZATION LOG

Keep track of sterilization-related activities using the sterilization log (**Appendix 8**) which should be posted in the reprocessing area. The following information should be tracked:

- Date.
- Name of health worker.
- Confirmation that the equipment was disassembled before undergoing CLEANING.
- Type of resuscitation equipment that is being sterilized.
- Whether equipment was wrapped or unwrapped. If wrapped, note the type of material.
- Mechanical indicators for cycle (time, temperature, pressure).
- Notation of whether chemical monitoring done with this cycle.
- Notation of the last time biological monitoring was conducted with this autoclave.

DISINFECTION STAGE (CONTINUED)

General information on wrapping and loading/unloading sterilizer

Always refer to the manufacturers' instructions for the sterilizer for specific directions on how to load and unload the sterilizer. Proper technique is important to achieve sterility of the equipment. General rules for sterilizer use include:

- Do not overload the sterilizer. The steam must have room to circulate freely.
- Never place items on the floor of the sterilizer and keep all trays and packs away from the chamber walls and ceiling.
- Allow packs to dry completely before unloading the sterilizer.

When wrapping items:

- Use double layer for paper (paper cannot be reused).
Caution: ink on newsprint may transfer to instruments.
- Use two double-layer wraps (four layers) for muslin.
- Do not use waterproof material for wrapping such as plastic or canvas
- Do not wrap packs too tightly. Air may become trapped inside the package and prevent complete sterilization.

General information for monitoring autoclave function^{11,12,20}

Steam sterilizers (autoclaves) must be expertly maintained to be effective. Monitoring can occur in three different ways.

Mechanical Indicators: Techniques for mechanically monitoring the sterilizer allow the user to assess the time, temperature, and pressure by looking at gauges or displays on the sterilizer. This is usually a printout or graph from the sterilizer. However, it can also be monitored in the form of a log (time, temperature, and pressure) kept by the person or persons responsible for the sterilization process.

Chemical Indicators: When using wrapped packs, chemical indicators assess physical conditions inside the sterilizer, such as temperature and pressure. Chemical indicators include heat-sensitive indicator tape or labels. These indicators should be used on the inside and outside of wrapped packs. External indicators verify that items have been exposed to the correct conditions of the sterilization process and that the specific pack has been sterilized. Internal indicators are placed inside a pack or container and tell if the item has been sterilized. An air-removal test (Bowie-Dick Test) must be performed daily in an empty prevacuum (dynamic-air-removal) sterilizer to ensure air removal.

Biological Indicators: Regular monitoring of the steam sterilization process with reliable biological indicators is strongly recommended. This process can directly determine whether the most resistant microorganisms are present. Biological indicator testing should occur weekly and as needed. Follow the manufacturer's directions for conducting biological indicator monitoring. In addition to routine testing, it is recommended that biological indicator monitoring occur when new trays or wrap material are used, new reprocessing personnel are trained, after repair of the sterilizer, and also after a change in sterilizer loading procedures. The indicator for steam sterilization is *Geobacillus stearothermophilus*.²⁰

A2 HIGH-LEVEL DISINFECTION

If sterilization is not available at the facility, HIGH-LEVEL DISINFECTION should be done to make the resuscitation equipment safe for reuse. HLD destroys all microorganisms except for some bacterial endospores.^{11,12,16}

There are several options for HLD. Select the best method based upon the resources at the health care facility. This guide discusses two methods of heat-based HLD (boiling and steaming) and two methods of chemical-based HLD (chlorine and glutaraldehyde). Each HLD process must be monitored carefully and used only for the specified amount of time for each activity to avoid damage to the equipment.

HIGH-LEVEL DISINFECTION LOG

For any method of HLD, keep track of the related activities using the HLD log (**Appendix 9**) which should be posted in the reprocessing area. The following information should be tracked:

- Date.
- Name of health worker.
- Confirmation that the equipment was disassembled before undergoing CLEANING.
- HLD method used (and concentration of chemical, if applicable).
- Type of resuscitation equipment that is being disinfected.
- Start time.
- End time.

Options for Heat-Based High Level Disinfection

► OPTION 1: BOILING

Boiling has been validated for neonatal resuscitation equipment by some manufacturers.²¹

WARNING: Never boil metal instruments with resuscitation equipment. This can cause rust to stain the silicone, and the metal could also pierce or otherwise damage the resuscitation equipment.

Materials and Equipment

- Boiling apparatus:
 - Boiling machine with lid + electricity source
 - Pot with lid + heat source
- Clean water (filtered if necessary)
- HLD log
- Timer/clock/watch
- High-level disinfected forceps
- PPE
 - Clean exam or utility gloves (for loading the boiling apparatus)
 - Sterile or high-level disinfected gloves (for handling equipment after boiling is completed)
 - Cap
 - Mask
 - Eye protection (from steam)
 - Apron
 - Protective boots

DISINFECTION STAGE (CONTINUED)

Instructions:¹²

STEP 1: Wear the same gloves used during the CLEANING step to add the (previously cleaned) resuscitation equipment to the empty boiler pan that was prepared in the PREPARATION step. Add clean water to the boiling apparatus. There should be at least 2.5 cm of water above the equipment. Ensure all equipment is submerged and full of water so that it does not float to the surface.

STEP 2: Close lid over boiling apparatus and bring water to a rolling boil.

STEP 3: Once water reaches a rolling boil, start timer or look at the time on a clock. In the HLD log (see **Appendix 9**), write down the start time when rolling boil begins.

STEP 4: Boil all items for 20 minutes. Write down the end time in the HLD log. Turn off boiling machine or remove pot from heat source.

STEP 5: After boiling for 20 minutes, remove objects immediately with high-level disinfected forceps. **Wear sterile or high-level disinfected gloves** before directly touching the equipment in order to maintain its disinfected status. Excess water can be removed from the equipment by gently shaking the equipment. **Wear a mask to avoid contaminating the disinfected equipment.**

Never leave boiled instruments in water that has stopped boiling. As the water cools and steam condenses, air and dust particles are drawn down into the container and may contaminate the instruments.

STEP 6: For information on options for drying the equipment, see the section DRYING AFTER HIGH-LEVEL DISINFECTION on **page 36** of this guide.

STEP 7: Drain water and wipe out boiler at the end of each shift. Wiping the boiling apparatus each day will help prevent the build-up of calcium carbonate (limescale) on the boiling apparatus.

The corresponding job aid for this HLD option can be found in **Appendix 10**.

Water quality and altitude affect the boiling process. Boiling the equipment for 20 minutes helps ensure that the microorganisms remaining on the equipment are destroyed.²²

► OPTION 2: STEAMING (NOT to be confused with autoclaving)

Steaming is another alternative to sterilization and has been recently validated by an independent laboratory at the request of a manufacturer of neonatal resuscitators.²³

Instructions:¹²

STEP 1: Use the steamer pan that was prepared in the PREPARATION step. Fill the bottom pan with approximately 1 L of clean water. Water should be refilled each time the steamer pan is used for steaming.

STEP 2: Wear the same gloves used during the cleaning step to place the clean resuscitation equipment in one of the steamer pans with holes in its bottom. Do not overfill the pan (see **Figure 9**).

STEP 3: Repeat this process until up to three steamer pans have been filled. Stack the filled steamer pans on top of the bottom pan containing the water for boiling.

STEP 4: A second empty pan without holes should be placed on the counter next to the heat source to receive the stack of newly steamed items once the steaming is completed (see **Appendix 11**).

STEP 5: Place a tightly fitting lid on the top pan and bring the water to a rolling boil. When water only simmers the temperature may not get hot enough to kill microorganisms.

STEP 6: When steam begins to come out between the pans and the lid, start the timer or note the time on a clock and write down the time in the HLD log (see **Appendix 9**).

STEP 7: Steam items for 20 minutes and write down the end time in HLD log. Remove the entire stack from heat source immediately.

STEP 8: Remove the top steamer pan and put the lid on the pan that was just below it (the pan which now appears on top of the stack). Gently shake excess water from the pan just removed.

Materials and Equipment

- Steamer pan with lid (such as a momo cooker). Must be deep enough to ensure that largest items will fit inside without creating a gap between the pans when they are stacked.
- Second pan (no holes) for drying process
- Heat source
- Clean water (filtered if necessary)
- HLD log
- Timer/clock/watch
- High-level disinfected forceps
- PPE
 - Clean exam or utility gloves (for loading the steamer)
 - Sterile or high-level disinfected gloves (for handling equipment after steaming is completed)
 - Cap
 - Mask
 - Eye protection
 - Apron
 - Protective boots

DISINFECTION STAGE (CONTINUED)

STEP 9: Put the pan with holes just removed onto the empty pan (without holes) that was set aside in Step 4. Repeat until all pans with holes are restacked on top of this empty pan (without holes) and the top pan with holes is covered with the lid. See **Appendix 11**. This step allows the items to cool and dry without becoming contaminated. Wear a mask to avoid contaminating the disinfected equipment.

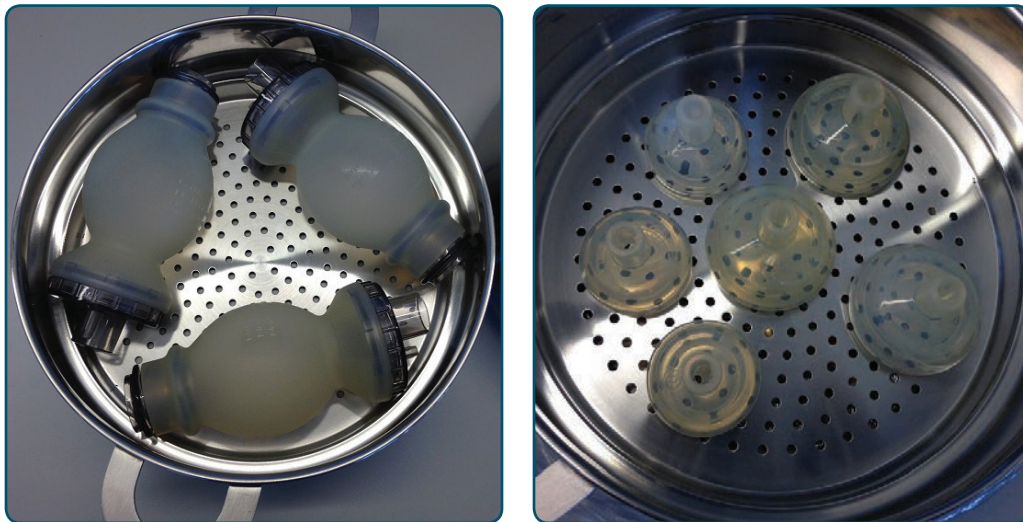
Any remaining water should be discarded from bottom pan that was used for steaming.

STEP 10: Allow items to air dry in the steamer pans (1 to 2 hours) before using.

STEP 11: Once items are thoroughly dry, using high-level disinfected forceps, transfer the dry items to the area where equipment will undergo INSPECTION, REASSEMBLY, and FUNCTION TESTING. If high-level disinfected forceps are not available, then wear sterile or high-level disinfected gloves to transfer dry items to the inspection area.

The corresponding job aid for this HLD option can be found in **Appendix 11**.

Figure 9. Examples of resuscitation bags and masks in preparation for steaming.



Options for Chemical High-Level Disinfection

WARNINGS for all chemical high-level disinfection:

- All chemical high-level disinfectants should be used in a well ventilated area away from patients.
- Do not use expired chemicals.
- Do not refill a commercial chemical container with either the same chemical or a different chemical. Refilling containers could lead to misinformation about the contents, the chemical concentration, or the expiration date. Further, refilling a container with a different chemical could cause a harmful chemical reaction.
- Never leave equipment soaking in a chemical disinfectant longer than the specified time. Overexposure to chemicals can damage equipment and will reduce its lifespan.
- Enzymatic detergent is **not** a disinfectant and should not be used for HLD. Examples of enzymatic detergent include Endozime® Bio-Clean and Enzol®.

DISINFECTION STAGE (CONTINUED)

► OPTION 1: CHLORINE 0.5%

Although not the preferred choice for reprocessing, chlorine-based products are the most commonly available and least expensive chemicals for HLD in facilities with limited resources.

Commonly available chlorine products include sodium hypochlorite (household bleach) and calcium hypochlorite powder. The amount of chlorine in these products varies and will impact the amount of water needed for dilution. **Appendices 5 and 6** of this guide outline the dilution instructions to prepare the chlorine solution 0.5% for HLD. This solution is strong enough to ensure that microorganisms are effectively destroyed.¹⁶ For more information on best practices on the use of chlorine, see the International Program on Chemical Safety's [chlorine monograph](#).²⁴

A few reminders for using chlorine:

Check the concentration of available chlorine¹⁷ in the chlorine product that will be used to prepare the chlorine solution 0.5% (see PREPARATION step).

Keep the chlorine solution in a plastic container:^{17,18} Long-term exposure to chlorine will corrode metal, so the chlorine solution 0.5% should be prepared in a container/bucket made of plastic. The container should be labeled "Chlorine Solution 0.5%", including date and time the solution was prepared. The container should be large enough to allow full immersion of the largest piece of equipment that will be disinfected.

Keep a lid on the container when not in use:¹⁸ The container should have a well-fitting lid. The lid is important for keeping the chlorine solution effective and to prevent staff, patients, and visitors from being exposed to chlorine fumes.

Keep out of direct sunlight¹⁸ and away from heat:¹⁶ Keep chlorine products and the diluted chlorine solution out of direct sunlight and do not use hot water to prepare the chlorine solution. Light and heat cause chlorine to degrade. This reduces the power of the chlorine solution to destroy microorganisms.

Change the chlorine solution daily or when it becomes cloudy, whichever occurs first.^{17,18}

Materials and Equipment

- Chlorine solution 0.5%
- Large plastic container (10 to 20 L, large enough to immerse largest piece of equipment, with tight-fitting lid)
- HLD log
- Timer/clock/watch
- High –level disinfected forceps
- PPE
 - Clean exam or utility gloves (for placing equipment in chlorine solution)
 - Sterile or high-level disinfected gloves (for handling equipment after disinfection is completed)
 - Cap
 - Mask
 - Eye protection
 - Apron
 - Protective boots

Instructions:

STEP 1: Wear the same gloves used during the CLEANING step to immerse the (previously cleaned and dried) equipment into the container of chlorine solution that was prepared in the PREPARATION step. All equipment must be submerged and full of chlorine solution to prevent any items from floating. Ensure there is at least 2.5 cm of liquid above the equipment. Any part of the equipment that is not completely immersed in the solution will not be disinfected. Cover the container.

STEP 2: Start timer or look at the time on a clock. Write down the start time of the procedure in the HLD log (see **Appendix 9**).

STEP 3: Soak for 20 minutes. Twenty minutes is long enough to destroy microorganisms when using a 0.5% chlorine solution. **Do not soak longer than 20 minutes** as this will damage and discolor the equipment. Write down the end time in the HLD log.

STEP 4: Use high-level disinfected forceps to remove equipment from chlorine solution. If high-level disinfected forceps are not available, **wear sterile or high-level disinfected gloves** to maintain the equipment's disinfected status. Wear a mask to avoid contaminating the disinfected equipment.

STEP 5: Shake off any excess chlorine solution and immediately place the equipment in the container with boiled water that has been cooled for rinsing. See the RINSING AFTER CHEMICAL HIGH-LEVEL DISINFECTION step in next section (**page 35**).

The corresponding job aid for this HLD option can be found in **Appendix 12**.

► OPTION 2: ACTIVATED GLUTARALDEHYDE 2.4%

Because the instructions may vary by manufacturer, it is important to carefully follow the directions provided by both the glutaraldehyde manufacturer and the resuscitation device manufacturer. Common brands of glutaraldehyde include Cidex® and MetriCide™.

The entire container of glutaraldehyde must be activated before use. Once activated, glutaraldehyde may be used for up to 14 days when stored and used according to the manufacturer's instructions. Over the course of the 14-day use period, the solution must be tested on a regular basis, using the manufacturer's test strips, to ensure that the solution is at the minimum effective concentration (MEC). Solution that falls below the manufacturer's MEC must be discarded immediately even if it has not reached the 14-day expiration date.

The glutaraldehyde solution should be kept in a plastic container with a tight-fitting lid. The container should be labeled "Activated Glutaraldehyde Solution 2.4%" including date and time the solution was prepared. The container should be large enough to fully immerse the largest piece of equipment that will be disinfected.

DISINFECTION STAGE (CONTINUED)

Fumes from glutaraldehyde can be very irritating. Use in a well ventilated area. For more information on best practices for use of glutaraldehyde, see the United States Occupational Health and Safety Administration's publication, "[Best Practices for the Safe Use of Glutaraldehyde in Health Care](#)."²⁵

Note that there is also a similar disinfectant product called ortho-phthalaldehyde, or OPA, which does not require activation and has different instructions for use.

Before using glutaraldehyde on resuscitation equipment, check the device manufacturer's instructions to ensure that the device can withstand disinfection with glutaraldehyde.

Instructions:

STEP 1: Wear the same gloves used during the CLEANING step to test the activated glutaraldehyde solution that was prepared in the PREPARATION step. It is important that the solution is above its MEC. Test the solution using a manufacturer's test strip prior to each use.

STEP 2: Immerse the previously cleaned and dried equipment into the activated glutaraldehyde container. All equipment must be submerged and full of glutaraldehyde solution to prevent any items from floating. Ensure there is at least 2.5 cm of liquid above the equipment. Any part of the equipment that is not completely immersed in the solution will not be disinfected. Cover the container.

STEP 3: Start timer or look at the time on a clock. Write down the start time of the procedure in the HLD log.

STEP 4: Check the device manufacturer's instructions for their recommendation on soaking time and temperature. If manufacturers' instructions are not available, check the glutaraldehyde manufacturer's instructions to achieve HLD. Leave the equipment in the solution for the required time and at the appropriate temperature. **Do not soak longer than indicated in the instructions** as this will damage and discolor the equipment. Write down the end time in the HLD log.

STEP 5: Use high-level disinfected forceps to remove equipment from the glutaraldehyde solution. If high-level disinfected forceps are not available, remove the equipment from the solution wearing **sterile or high-level disinfected gloves** to maintain the equipment's disinfected status. Wear a mask to avoid contaminating the disinfected equipment.

Materials and Equipment

- Activated glutaraldehyde 2.4%
- Large plastic container (10 to 20 L, large enough to immerse largest piece of equipment, with tight-fitting lid)
- HLD log
- Timer/clock/watch
- Thermometer and manufacturer test strips (for testing the solution)
- High-level disinfected forceps
- PPE
 - Clean exam or utility gloves (for placing equipment in glutaraldehyde solution)
 - Sterile or high-level disinfected gloves (for handling equipment after disinfection is completed)
 - Cap
 - Mask
 - Eye protection
 - Apron
 - Protective boots

STEP 6: Shake off any excess glutaraldehyde solution and immediately place the equipment in the container with boiled water that has been cooled. See rinsing instructions for chemical HLD in next section.

The corresponding job aid for this HLD option can be found in **Appendix 13**.

B

RINSING AFTER CHEMICAL HIGH-LEVEL DISINFECTION

It is very important to thoroughly rinse resuscitation equipment after chemical HLD. Chemicals remaining on the equipment could damage the equipment or be ventilated into the infant's airway. In order to thoroughly remove the chemical from the devices, the equipment should be rinsed in three separate volumes of boiled water. This can be achieved by filling three separate buckets or by refilling the same rinse bucket three times.

Water used for rinsing of chemical disinfectant should **not** be used afterwards for any other purpose as it will contain traces of the chemical.

Instructions:

STEP 1: During the last step of CHEMICAL HIGH-LEVEL DISINFECTION, equipment that had been soaking in the chemical solution was removed from that container and placed in the "Boiled Water" container.

STEP 2: **Wear sterile or high-level disinfected gloves** to rinse each piece of equipment thoroughly in boiled water that has been cooled. Rinse three times by using three separate containers of boiled water to make sure that all the chemical is fully removed from the equipment. Immerse the equipment completely in the first container of boiled water and move it around, shake off excess water and then immerse it in the second container and move it around. Repeat in the third container. Ensure that gloves have also been rinsed free of chemicals. Wear a mask during this process to avoid contaminating the disinfected equipment.

STEP 3: Shake off excess water and follow drying protocol in next section.

Materials and Equipment

- Boiled water that has been cooled (prepared per instructions in PREPARATION STEP)
- Three large plastic containers (10 to 20 L, large enough to immerse largest piece of equipment, with tight-fitting lid)
- High-level disinfected forceps
- PPE
 - Sterile or high-level disinfected gloves
 - Cap
 - Mask
 - Eye protection
 - Apron
 - Protective boots

DISINFECTION STAGE (CONTINUED)

C DRYING AFTER HIGH-LEVEL DISINFECTION

After any type of HLD, the equipment must be thoroughly dried before inspection, reassembly, testing, and use. Equipment can be either air dried or wipe dried.

METHOD	PROS	CONS
OPTION 1: WIPE DRYING	<ul style="list-style-type: none"> • Dries equipment quickly. • Reduces risk of exposing equipment to dust, insects, and other environmental contaminants. 	<ul style="list-style-type: none"> • Requires more materials as equipment can only be dried with sterile gauze or autoclaved linen.
OPTION 2: AIR DRYING	<ul style="list-style-type: none"> • Requires fewer materials. 	<ul style="list-style-type: none"> • Equipment dries slowly (1 to 2 hours, possibly more depending upon humidity). • Increases risk of exposing equipment to dust, insects, and other environmental contaminants while drying.

► OPTION 1: WIPE DRYING

This is the preferred method for drying after HLD but only if use of sterile gauze or autoclaved linen (lint-free cloth) can be guaranteed.

Wear sterile or high-level disinfected gloves, a mask, and a cap to use sterile gauze or autoclaved linen to thoroughly dry all the internal and external surfaces of the equipment. Once each component is thoroughly dry, place it in an area that has been high-level disinfected in preparation for INSPECTION.

► OPTION 2: AIR DRYING

Air drying should be done in a place that is protected from dust, insects, and other environmental contaminants. Items that were disinfected by steaming can be dried in the steamer pan following the instructions outlined on **page 30**. While no method can completely protect the resuscitation equipment from these exposures, the following two options are possible methods to air dry resuscitation equipment:

a) Wear sterile or high-level disinfected gloves, a mask, and a cap to place the equipment in a plastic or metal container that has undergone HLD. The lid must be partially off to allow for air flow. Wear a mask during this process to avoid contaminating the disinfected equipment.

b) Wear sterile or high-level disinfected gloves, a mask, and a cap to place the equipment on a high-level disinfected surface under a wire mesh dome to protect from pests. See **Figure 10** for an example of a wired mesh dome. Care must still be taken to protect from dust and other environmental contaminants. The wire mesh dome should also be high-level disinfected on a regular basis (for example: washed with soapy water, dried, and wiped with clean gauze soaked in chlorine solution 0.5%). Wear a mask during this process to avoid contaminating the disinfected equipment.

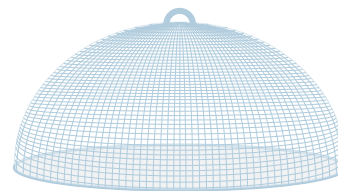


Figure 10. A wire mesh dome used to cover food, such as this one, can be used to protect equipment while air drying.

4 POST-DISINFECTION STAGE

A INSPECTION

After equipment has fully dried following STERILIZATION or HIGH-LEVEL DISINFECTION, each component of the device should be inspected to ensure it is ready for use and undamaged. INSPECTION should be done before REASSEMBLY to ensure that all the components are clean and undamaged. This step should be conducted on a surface that has undergone HLD.

The number of components were counted when the bag was disassembled. **Wear sterile or high-level disinfected gloves, a mask, and a cap** to count the pieces of resuscitation equipment. The count should match that conducted during DISASSEMBLY.

Inspect each piece of equipment (bag, mask, suction device). Ensure that the components of the ventilation bag are all from the same model. It is important not to mix the components from different manufacturers or models, even if they look similar, to ensure that components function properly.

Inspect for:

1) Damage:

- Cracks or tears in the bag, suction device, and mask/mask rim.
- Torn membranes and valves.

2) Missing parts:

Masks have different rim types, inflatable cushioned rims or molded cushioned rims. The rim is important for ensuring a tight seal around the infant's mouth and nose. For masks that require an inflatable cushioned rim, ensure that the rim is present on the mask and in working order (see **Figure 11** for an example).

3) Membranes that are stuck together.

4) Residual contamination or soil.

5) Residual moisture.

6) Mineral deposits.



Figure 11. The photo on the left shows a mask that is missing the inflatable cushioned rim and cannot create a tight seal around the infant's mouth and nose. The photo on the right shows the same mask with the cushioned rim intact. Gloves should always be worn when function testing medical equipment.

Photo credit: PATH/Manjari Quintanar Solares

POST-DISINFECTION STAGE (CONTINUED)

If there is damage to any component, remove it from service. For more information on removing an item from service, see **page 40** of this guide.

If any components are not clean, restart reprocessing of these components with the CLEANING Step. If there are mineral deposits, follow the instructions on **page 22** of this guide for removing mineral deposits with vinegar, and repeat the STERILIZATION/HIGH-LEVEL DISINFECTION step afterwards.

Once inspection is complete and each piece is confirmed to be in working order and clean, move on to REASSEMBLY.

B

REASSEMBLY

This step should be conducted on a surface that has undergone HLD.

To aid with reassembly, post a photo/diagram in the reprocessing area that shows the resuscitator components in their appropriate positions.

Wear sterile or high-level disinfected gloves, a mask, and a cap to reassemble the (previously inspected) components of the ventilation bag and suction device.

Check that the components belong to the same resuscitator model. Do not mix components from different models and manufacturers. Follow the manufacturer's instructions to correctly place valves and membranes, and ensure that all components have been properly fitted together. Correct reassembly of the device is essential to ensure that it functions properly. This step will become easier with practice as user becomes more familiar with the resuscitator model.

For all suction devices, check that the top of the suction device fits tightly onto the bottom.

C

FUNCTION TESTING

Function Testing for the Ventilation Bag and Mask

After INSPECTION and REASSEMBLY, the device should be function tested to ensure it is ready for use. Function testing should be conducted both after reassembly and prior to use.

Function testing will help determine if there are problems such as:

- Components are fitted incorrectly.
- Components are blocked or stuck open.
- The assembly is leaking small amounts of air.

This step should be conducted on a surface that has undergone HLD. **Wearing sterile or high-level disinfected gloves, a mask, and a cap**, follow these three steps and see **Figures 12, 13, and 14**.

STEP 1: Put the mask on the ventilation bag. Squeeze the bag and **look** for the valve in the patient outlet to open with each squeeze. This shows the device is ready to deliver air to a patient. See **Figure 12**.

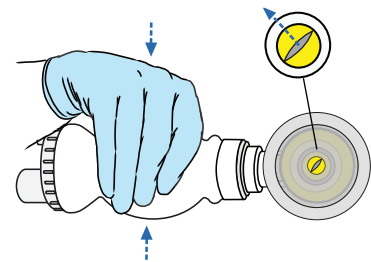


Figure 12.

STEP 2: Seal the mask tightly to the palm of one hand and squeeze hard enough to open the pressure release valve. **Listen** for the sound of air escaping. This shows that air that cannot be delivered safely to the baby will escape through the pressure release valve. See **Figure 13**.

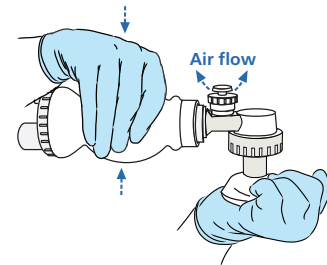


Figure 13.

STEP 3: Maintain the tight seal and check that the bag reinflates after each squeeze. This shows that fresh air will enter the bag through the inlet valve. See **Figure 14**.

STEP 4: If any step fails, disassemble and reassemble the device and test the functionality again. If it still fails, remove the device from service and follow instructions on **page 40**.

Function Testing for the Suction Device

This step should be conducted on a surface that has undergone HLD. **Wear sterile or high-level disinfected gloves, a mask, and a cap,** and follow these steps:

STEP 1: Ensure that the top of the suction device fits tightly onto the bottom.

STEP 2: Check the vacuum of the device: squeeze the bottom portion of the suction device and hold the squeeze. Block the opening of the tip against the palm of one hand and release the squeeze. The suction device should not expand until the tip is unblocked. See **Figure 15**.

STEP 3: If there is no vacuum on the suction device, open the suction device and close it up again to ensure that the pieces fit together tightly. Follow the process to check the vacuum once more. If it fails again, remove it from use and follow instructions on **page 40**.

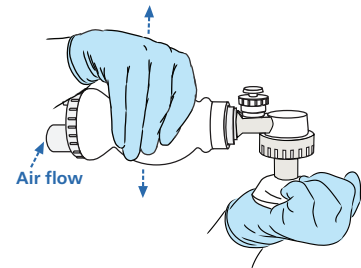


Figure 14.

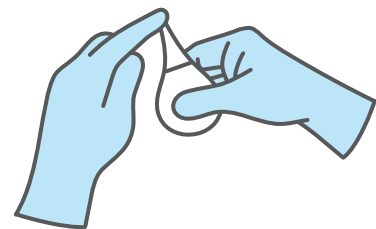


Figure 15.

Figures 12-15: American Academy of Pediatrics, Helping Babies Breathe, 2016.

POST-DISINFECTION STAGE (CONTINUED)

Failed equipment

If, after INSPECTION, REASSEMBLY, and FUNCTION TESTING, the devices do not work properly, remove any devices that do not function correctly from service immediately. Set them aside in a space that is specifically intended for failed equipment and away from functional equipment. Be certain that these devices do not get mixed in with functioning devices. Put them in a separate bag or container and clearly label it “Malfunctioning Equipment. Do NOT Use.” The unit or facility should develop a written plan detailing the process for failed equipment. A supervisor should check failed devices in case the failure is due to error in reassembly or some other issue that is easily corrected.

When the malfunction of the resuscitation equipment is due to an obvious defect, such as a torn membrane, other pieces of that same resuscitator may be reusable as spare parts for other ventilation bags of the same model. Designate a method to store and label parts that can be reused. The spare parts must be labeled with the part name/type and model name and manufacturer name. Parts are not interchangeable between manufacturers or models. Follow any additional reporting protocols required by the facility.

Reuse period

The lifespan of a device depends on how many times the equipment is used and how well it is reprocessed. Manufacturers commonly state that resuscitation devices have a 5 year lifespan, but with good quality care, the devices can be functional for longer. It is important to follow the reprocessing steps as described in this guide. Soaking in dirty water, soaking in chemicals for longer than the recommended time, and boiling/steaming for too long can all significantly shorten the lifespan of resuscitation devices and cause the equipment to become discolored.

D STORAGE

After equipment has undergone inspection, reassembly, and function testing, store the devices until they are needed.

- **Wear sterile or high-level disinfected gloves, a mask, and a cap.**
- Place equipment into a previously high-level disinfected storage container with lid.

Storage containers should be made of metal or plastic and have a tight-fitting lid. They must be kept clean and undergo HLD on a regular basis. Another option for storage is to wrap resuscitation equipment in autoclaved linen.²⁶ If possible, once equipment is inside the storage container or the autoclaved linen wrap, it should be placed inside a closed cabinet to further protect the equipment from dust and other environmental contaminants. However, resuscitation equipment must be immediately accessible to staff, not locked away.

Never use cardboard boxes or the manufacturer’s original packaging to store equipment that has been high-level disinfected or sterilized. Cardboard generates dust and can house pests.

It is important to determine the facility’s policy on the shelf-life of reprocessed equipment. This means that if the equipment is not used for a long period of time, it may need to be reprocessed again to ensure that it remains clean and ready for use. Consider whether it makes sense for the

facility to implement a “first in, first out” system so that equipment does not remain in storage too long without being used. “First in, first out” means that as equipment is reprocessed it is placed in storage behind the equipment that was previously reprocessed. Equipment is removed from the front of storage as it is needed. This helps keep the equipment in a continuous rotation and no piece of equipment remains in storage too long. Ensure that all non-functional equipment has been removed from the area.

Storage containers and their lids should undergo HLD at least every week or more frequently if they appear dusty or soiled. Metal or plastic storage containers should be washed in soapy water, rinsed thoroughly, dried with a clean cloth, and then wiped inside and outside with a clean cloth soaked in chlorine solution 0.5%. Air dry completely and place the sterilized or high-level disinfected equipment back inside the box and close the lid.^{11,27} If using autoclaved linen for storing equipment, wash and then autoclave the linen at least once a week or more frequently if it appears dusty or soiled.

Neonatal resuscitation equipment that is taken out of the storage container and brought to the bedside in preparation for delivery should be placed on a recently high-level disinfected surface. Even if the equipment was not used, it must still undergo some level of reprocessing since it has been exposed to microorganisms in the delivery area. Wipe the external surface of the unused equipment with chlorine solution 0.5% and allow it to dry before returning it to storage. Equipment that was used during the delivery must be fully reprocessed.

SECTION 5

REPROCESSING TRAINING AND SUPERVISION

At health facilities, staff responsible for reprocessing of neonatal resuscitation equipment vary and may include nurses/midwives, nursing students, central processing staff, and custodial staff. In some countries, skilled birth attendants at the community level are also trained to provide basic neonatal resuscitation and must reprocess their own resuscitation equipment. To guarantee that basic neonatal resuscitation equipment is always ready for use and does not pose an infection risk to babies, it is very important to consistently train all staff will be responsible for reprocessing the equipment, no matter if this duty is permanent or temporary.

When reprocessing techniques are passed from person to person in an informal way, inconsistent transmission of information may result and unintentionally lead to poor reprocessing practices. Poor reprocessing practices increase the risk of health-care-associated infection. To increase the consistency of reprocessing knowledge and practices, the health facility or unit can use this guide to customize the reprocessing guidelines specific to the reprocessing materials and equipment typically available at the facility or unit. Ideally, units in the same facility (e.g., labor ward, special newborn care unit, etc.) should align the reprocessing methods they will use to avoid confusion and to help rotating staff adhere to the guidelines. The customized guidelines should:

- Identify the primary method by which neonatal resuscitation equipment will undergo sterilization or HLD.
- Identify the back-up methods of HLD in case the primary method is unavailable.
- Outline the preferred workflow.
- Describe policies for malfunctioning equipment and equipment replacement.

Facilities should make reprocessing guidelines and manufacturer recommendations easily available to those responsible for reprocessing. Guidelines, along with job aids, should be posted in the reprocessing area, and manufacturer instructions (for devices and for chemicals) should be kept nearby for reference. In settings where skilled birth attendants at the community level are trained to provide neonatal resuscitation, written and pictorial reprocessing guidelines should be provided to them along with their neonatal resuscitation devices.

This guide provides recommendations for the formal reprocessing training curriculum that should be in place at each unit that reprocesses neonatal resuscitation equipment within a facility. This should include an initial training session and regular refresher trainings for any staff member or skilled birth attendant at the community level responsible for the reprocessing of neonatal resuscitation equipment.

Regular supervision for reprocessing practices is necessary to ensure that all those responsible for reprocessing are consistently following good reprocessing practices. It is recommended that health facility administrators designate a reprocessing champion who can provide support to those who are responsible for reprocessing medical equipment. Someone who works at the facility on a regular basis would be an ideal reprocessing champion so that they are consistently available for consultation. The champion should be someone who is very familiar with infection control and who has reprocessing experience. The champion should be able to answer infection control and reprocessing questions, provide reprocessing supervision when needed, conduct formal reprocessing trainings, provide process improvement recommendations, and guide/oversee requests for equipment replacement.

Training²⁸

1. Healthcare facilities should provide training to all personnel who reprocess neonatal resuscitation devices. Training should be required and provided in the following instances:
 - Prior to joining a unit within the facility (whether on permanent or temporary duty).
 - Refresher at least once a year.
 - When changes occur, such as the introduction of new equipment or procedures or if the manufacturer implements changes to the instructions for use.
2. Before staff conduct reprocessing independently, a supervisor or trainer must confirm the staff member's competency by observing that reprocessing of neonatal resuscitation equipment is done using the correct technique.
3. Trainings and competencies should be documented by the health care facility.
4. Manufacturers' instructions for medical equipment, chemical disinfectants, and reprocessing equipment (i.e., autoclave, boiling machine) should be easily available to staff. Staff should refer to the instructions for use that were included with the new resuscitation equipment to ensure that the facility's selected disinfection method is suitable for the device. The disassembly and reassembly illustrations for each type of resuscitator should be photocopied and posted in the reprocessing area.

Trainings should include participatory discussion of the following concepts to ensure correct understanding:

Infection risk

- Each piece of equipment that has been used or has been placed outside of its storage container for a prolonged time poses a risk of infection to the baby. Even when a device might appear clean to the naked eye, at the microscopic level there are microorganisms on the outside and inside surfaces of the device. Staff may sometimes have the perception that certain pieces of equipment are cleaner or dirtier than others. For example, the suction device may be perceived to be dirtier than the ventilation bag because one can clearly see secretions in the suction device.¹ However, microorganisms make their way into and can survive inside the ventilation bag as well. Therefore, it is important to communicate to those responsible for reprocessing that every piece of resuscitation equipment must be thoroughly reprocessed before reuse.
 - Inadequate reprocessing between patients may result in the retention of blood, tissue, and other biological debris on the equipment. Microorganisms can survive sterilization or disinfection if the reprocessing steps are not followed as described. This can lead to health-care-associated infections.⁵
-

Rationale for reprocessing steps

- The purpose of each step should be explained in detail and defined as a series of actions that must occur sequentially in order to be effective.
- Staff are more likely to perform each step adequately if they understand the rationale.
- Emphasis should be given to the need to reprocess equipment immediately in order to prevent debris from becoming stuck to the equipment. Once debris/secretions are dry, they are very difficult to remove and they harbor microorganisms.
- In general, resuscitation equipment should not be reprocessed at the same time with other types of equipment because metal equipment, for example, can discolor the silicone and pierce the bag or suction device. Resuscitation equipment should be kept separate from other types of equipment during IMMEDIATE PRE-CLEANING, DISASSEMBLY, CLEANING, RINSING, and DRYING. Also, do not mix equipment that is boiled or soaked in chemicals during HIGH-LEVEL DISINFECTION. Resuscitation equipment may be mixed with other equipment during steaming or sterilizing (autoclaving) as long as the pieces of equipment are not touching (do not wrap with non-resuscitation equipment in the autoclave).

Rationale for precise chemical dilution, particularly chlorine

- Chemical dilution instructions must be followed very carefully to achieve the correct strength. A solution that is diluted beyond what is indicated will not be effective in killing microorganisms. A solution that is more concentrated than indicated can shorten the lifetime of the equipment.
- Chlorine products have different amounts of available chlorine. This will impact the amount of water that should be added. It is important to check the product label to know the amount of available chlorine it has.
- The final strength of chlorine solution used for neonatal resuscitation equipment in any scenario in this guide is 0.5%.

Practice of disassembly and reassembly of the ventilation bag, and practice of function testing

- Disassembly and reassembly of the resuscitators should be demonstrated. Staff should practice several times so that they feel competent in doing this process.
 - Function testing should be demonstrated and practiced by staff. The rationale for each step of function testing should be described and both visual and audio cues should be observed (for example, see the valve opening and listen for air escaping from the pressure release valve).
-

Device lifecycle and facility policy on malfunctioning equipment

- Staff should be able to distinguish a single-use device from a reusable device. Differences that will help them recognize the different type of devices should be pointed out (a reusable device can be disassembled in order to access all surfaces which can be contaminated; single-use devices have inscriptions on the device surfaces that say “single-use,” etc.). Note that closed, opaque, rubber suction bulbs that cannot be opened up are always to be considered as single-use suction devices.
 - Single-use devices should be discarded after use.
 - Taking good care of the equipment and following the reprocessing steps correctly will help the device reach its stated lifetime (and maybe longer).
 - Facility policy on malfunctioning equipment should be defined:
 - The location where malfunctioning devices will be placed so that they are not confused with functional equipment should be demonstrated.
 - The person who will make a secondary check to confirm the equipment is not working (as opposed to incorrectly assembled) should be defined.
 - The policy defining whether spare parts are saved for use on other resuscitators of the **same model should be outlined. If spare parts are saved, their location should be demonstrated.**
 - The facility policy for disposing of malfunctioning equipment and ordering a replacement should be stated.
-

Regular procedure for checking that enough resuscitation equipment is at hand

- The unit’s policy for checking at the beginning of each shift to ensure that there is enough resuscitation equipment in working order should be explained.
 - No resuscitation equipment should be left to soak in liquid (chemical or water) beyond the time recommended in this guide.
-

Location of reprocessing guidelines

- The job aids should be posted in the reprocessing area and the guidance should be accessible nearby for reference. Those responsible for reprocessing should be shown where the reprocessing job aids are posted and the guidelines are stored.
 - This area should be checked regularly to ensure that the job aids and guidelines are legible and not torn or missing.
-

Audit and Feedback²⁸

- Adherence to reprocessing policies and procedures should be regularly monitored and documented, assessing all reprocessing steps including (but not limited to):
 - Proper and consistent use of PPE.
 - Performing cleaning without delay before initiating sterilization or disinfection.
 - Adherence to the manufacturers' instructions or the instructions found in this guide for chemical disinfectants in regard to dilution, contact time, storage, and shelf-life.
 - Regular evaluation of autoclave performance (use of chemical and biological indicators, assessment of the physical performance of the autoclave, and record keeping of time/temperature/pressure).
- Regular monitoring should take place in all units of the health care facility where reprocessing is performed.
- After audits, staff responsible for reprocessing should receive feedback in regard to the observed adherence to established reprocessing procedures/policies.

Infection Control Policies and Procedures²⁸

- Facilities should ensure that staff have sufficient time allocated for reprocessing in order to ensure that all steps are followed, including drying and proper storage.
- Facilities should outline policies and procedures for identifying devices that have been fully reprocessed and are ready for use, such as storage of reprocessed devices in a specific area of the unit.
- Facilities should have a plan to guide the staff when a reprocessing omission or error has occurred. Whenever possible, the potential risk of infection should be determined. The equipment should be reprocessed properly before being used on another patient.
- Facilities should make an effort to track infants who were resuscitated with an improperly reprocessed device, and outline a plan to notify their family caregiver(s) and provide follow-up to the infants.
- Reprocessing and infection-control policies and procedures as well as the facility's reprocessing capabilities must be considered prior to purchasing or introducing new medical equipment. The reprocessing champion or infection control committee should participate in the decision-making process.
- Documentation of reprocessing activities as well as maintenance records for reprocessing equipment (such as autoclaves) should be kept. Further, sterilization records and chemical disinfectant logs should also be kept. Records will help demonstrate that sterilization monitoring was carried out regularly and that chemical disinfectants were checked and replaced correctly.
- Manufacturers' recommendations for maintenance and repair of reprocessing equipment (e.g., autoclave, boiling machines) and medical equipment should be followed.
- Facilities need to supply units with enough resuscitation equipment to help ensure that reprocessing steps are not shortened or skipped.

SECTION 6

FURTHER CONSIDERATIONS FOR FACILITY ADMINISTRATORS AND MINISTRY OF HEALTH OFFICIALS

Reprocessing medical equipment, specifically neonatal resuscitation equipment, is an important component in providing patients with the best quality of care and keeping them safe from hospital-acquired infections. Multiple factors influence the ability of health facility staff to undertake reprocessing of medical equipment, and to do so in a manner that ensures the safety of future patients. Some of these factors have been identified, including having sufficient availability of resuscitation equipment to meet the needs of the units' patient volume.¹

Each facility should review existing literature, such as this guide, and customize their reprocessing guidelines for neonatal resuscitation equipment. Since reprocessing materials and equipment can vary within facilities or within the same district/county/province, the facility or unit guidelines should be facility- or unit-specific, taking into consideration the availability of reprocessing equipment/materials. Clear guidance should be included about the methods of sterilization or HLD that should be used as the primary method and what secondary methods are available if the primary method cannot be undertaken.

The following factors have been identified as barriers to medical equipment reprocessing in resource-limited settings. When developing a reprocessing plan, the following points should be taken into consideration:

1. *Materials and resources.* A shortage of materials and resources, in general, is a de-motivating factor among health care workers. Further, a lack of resources does not inspire confidence in either the health care workers or the patients. A systematic review of the literature by Willis-Shattuck, et al. found that a lack of resources, among several other factors, was a key de-motivator and component of decisions by health workers to migrate to other countries.²⁹

2. *Medical equipment.* A shortage of medical equipment impedes effective patient care. Missing equipment can prevent patients from receiving life-saving treatment, and malfunctioning equipment used because no replacement equipment is available may lead to poor outcomes or death.

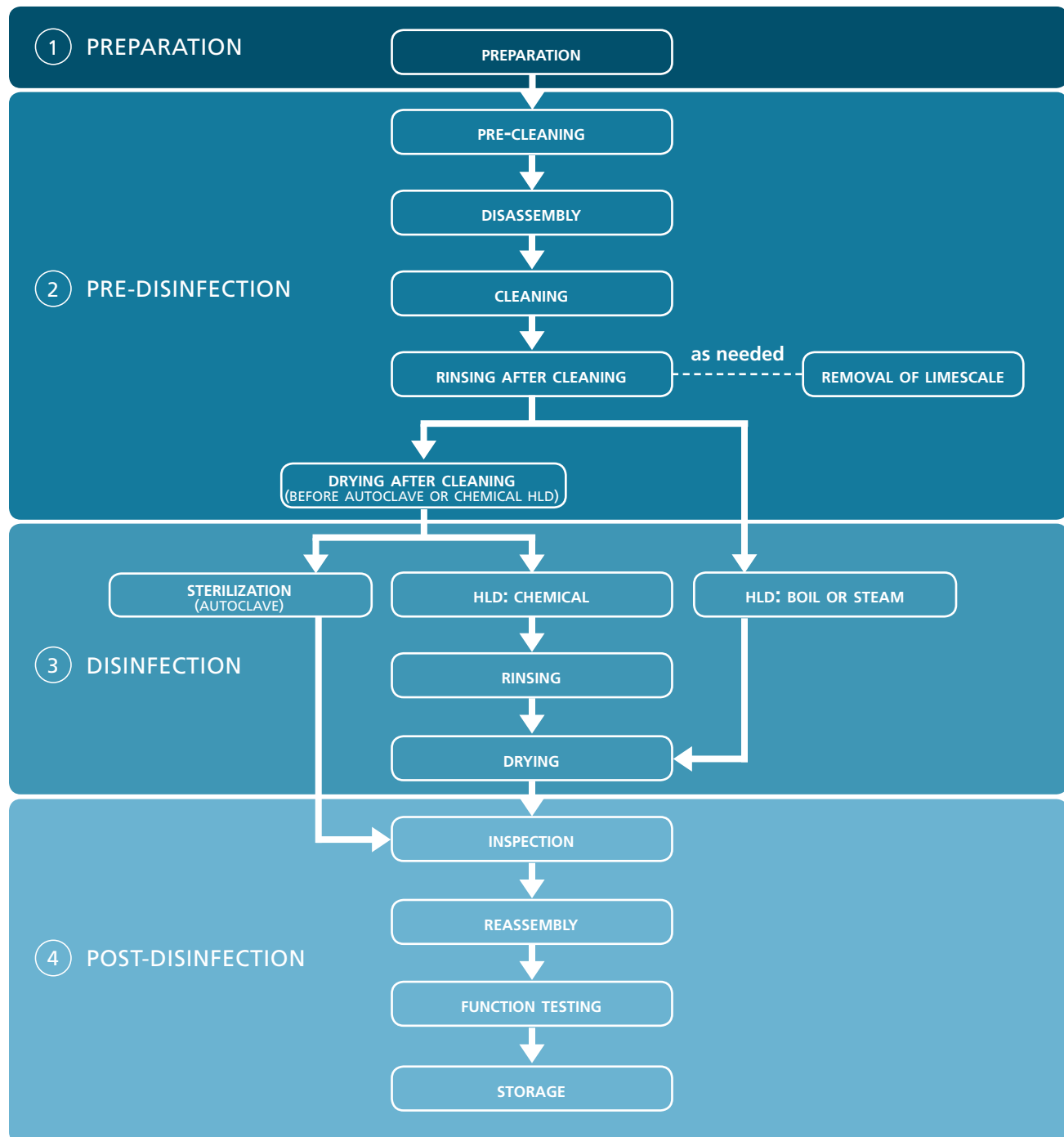
In addition to planning for day-to-day equipment needs, it is also important to determine what additional equipment will be needed in the case of missing or malfunctioning equipment. The procurement requirements for neonatal resuscitation equipment are unique and can be complex. Basic neonatal resuscitation requires five different commodities: ventilation bag, two masks (preterm and term sizes), suction device, training manikin, and training materials. Further, resuscitation equipment needs are quantified not only by the number of births per year, but also by the number of delivery rooms and neonatal intensive care units (or special newborn care units), the levels of facilities that provide delivery services, the number of staff who are qualified to perform resuscitation, the number of medical or nursing students who require training on the manikins, etc.³⁰ It is necessary to have enough functional resuscitation equipment available in each unit that provides resuscitation to accommodate not only the number of patients that may need resuscitation, but also to consider the equipment that might be going through reprocessing and thus cannot be used at a given time. Estimated numbers will also have to take into account malfunctioning equipment due to loss of parts or faulty reprocessing. In order to provide guidance on the procurement of neonatal resuscitation commodities and reduce confusion and uncertainty, PATH has developed a neonatal resuscitation quantification tool (<http://www.path.org/publications/detail.php?i=2401>)³⁰ and a neonatal resuscitation procurement toolkit (<http://www.path.org/publications/detail.php?i=2617>)³¹ to help with resource planning for neonatal resuscitation programs.

- 3. Reprocessing supplies and materials.** A shortage of reprocessing supplies and materials prevents proper reprocessing of medical equipment. Reprocessing is a multi-step process which requires a moderate amount of equipment to undertake, even in resource-limited settings. These pieces include, but are not limited to, appropriate PPE, clean water, access to autoclave for sterilization or to chemical or physical methods of disinfection, multiple containers (buckets), gloves, scrub brushes, and gauze/cloth. See **Appendix 2** for a comprehensive list of materials and equipment. Reprocessing steps, materials, and equipment intend to protect not only the patient, but also the person doing the reprocessing. Without fully completing the reprocessing steps, the equipment cannot be assured to be safe for patient use.
- 4. Reprocessing training and educational resources.** A lack of reprocessing training and refresher training prevents workers from knowing the steps they should follow and fully understanding why each step of the process is necessary. Without this background information, steps may be seen as unimportant or unnecessary and will be shortened or skipped. The facility's infection control committee should play a key role in ensuring that reprocessing training is occurring on a regular basis. A reprocessing champion within the unit or facility should be identified to provide support to workers responsible for reprocessing. Someone who works at the facility on a regular basis would be an ideal reprocessing champion so that they are consistently available for consultation. This champion would ideally be someone who is very familiar with infection control and who has reprocessing experience. The champion should be able to answer infection control and reprocessing questions, provide reprocessing supervision, conduct formal reprocessing trainings, provide process improvement recommendations, and guide/oversee requests for equipment replacement. The facility or the reprocessing champion should ensure that all types of resuscitators in their facility are documented and listed by type, size, and quantity along with type-specific accessories (things not covered within this guide, such as oxygen accessory valves, reservoir bags, and tubes). Devices should be regularly reviewed and those that are overly worn, are single-use, or are generally incompatible with the other devices should be removed from service.
- 5. Time.** Protecting the dedicated time of the person or people assigned to reprocessing is important to ensure that reprocessing occurs regularly. Reprocessing should be viewed as a planned and scheduled part of the workload rather than as an activity to be done in addition to regular duties. When perceived to be an extra responsibility and no time has been allotted for reprocessing, the work is often conducted in a hurried fashion where steps are shortened or skipped or equipment is left soaking or boiling for too long, which damages and significantly shortens the lifespan of the equipment. Inadequate reprocessing of medical equipment can lead to the spread of hospital acquired infections. Further, time constraints which impact reprocessing also lead to equipment shortages, meaning that the equipment is not ready and available when needed. In facilities where there are not staff devoted exclusively to reprocessing, it is recommended that one person be assigned to reprocessing for each shift each day. Regular reprocessing experience, with protected time for the activity, will help staff become more experienced with reprocessing, will help them become more familiar with the disassembly and reassembly of complicated medical equipment, and will provide the time needed to complete the process correctly.
- 6. Space.** An area that is specifically intended for reprocessing must be designated within the unit or facility. In an ideal situation, there would be separate reprocessing rooms for "dirty" (contaminated) and "clean" (sterilized/high-level disinfected) equipment. See **Figure 1** for the reprocessing space layout. When such expansive space is not available, separate areas of a reprocessing room must be designated for these processes to avoid recontamination of clean equipment. When planning new reprocessing space, administrators should consider issues of space, ventilation, protection from dust, and appropriate storage for reprocessing equipment and chemicals. Although some facilities have made use of outdoor space for reprocessing, this is not recommended because it exposes medical equipment to further dust and debris, and compromises the effectiveness of chemicals in direct sunlight and heat.

APPENDICES

APPENDIX 1

Steps to Reprocess Neonatal Resuscitation Equipment



HLD = High-level disinfection

APPENDIX 2 Checklist of reprocessing materials and equipment needed for each reprocessing step

MATERIALS/ EQUIPMENT	CHOOSE EITHER STERILIZATION OR HIGH-LEVEL DISINFECTION (HLD)										INSPEC- TION/ FUNCTION TESTING/ REASSEMBLY	STORAGE
	PREPARA- TION	IMMEDIATE PRE-CLEAN- ING	DISASSEM- BLY	CLEANING	RINSING AFTER CLEANING	DRYING AFTER CLEANING	STERILIZA- TION	HLD	RINSING AFTER CHEMICAL HLD	DRYING AFTER HLD		
Reprocessing guidelines and job aids	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clean gloves (exam or utility)	✓	✓	✓	✓	✓	✓	✓	✓				
Sterile or high-level disinfected surgical gloves							✓	✓	✓	✓	✓	✓
Cap	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mask	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Eye protection (goggles, face shield)	✓	✓	✓	✓	✓	✓		✓	✓			
Apron (plastic)	✓	✓	✓	✓	✓	✓		✓ (if chemical)	✓ (if chemical)			
Protective footwear (rubber boots or shoes)	✓	✓	✓	✓	✓	✓		✓	✓			
Measuring cup		✓						✓ (if chemical)				
Precision weighing scale or spoon (tablespoon or teaspoon)		✓ (if using dry chlorine powder)						✓ (if using dry chlorine powder)				
Plastic stirring utensil		✓						✓ (if chemical)				
Small plastic container with lid (up to 1 L)*		✓										
Large plastic container(s) (buckets) with lid (10 to 20 L)*				✓	✓			✓ (if chemical)	✓ (if chemical)			
Forceps (high-level disinfected)								✓	✓			
Masking tape and permanent markers				✓	✓			✓ (if chemical)	✓ (if chemical)			✓
Timer/clock/watch							✓	✓				
Sterilization or HLD log (print-out or notebook)							✓	✓				
Thermometer								✓ (with glutaraldehyde only)				
Manufacturer test strips								✓ (with glutaraldehyde only)				

* Containers used to prepare chemical solutions should be plastic to avoid rusting and/or other chemical interactions.

MATERIALS/ EQUIPMENT	CHOOSE EITHER STERILIZATION OR HIGH-LEVEL DISINFECTION (HLD)										INSPECTION/ FUNCTION TESTING/ REASSEMBLY	STORAGE
	PREPARATION	IMMEDIATE PRE-CLEANING	DISASSEMBLY	CLEANING	RINSING AFTER CLEANING	DRYING AFTER CLEANING	STERILIZATION	HLD	RINSING AFTER CHEMICAL HLD	DRYING AFTER HLD		
Clean water		✓		✓	✓			✓				
Boiled water									✓ (if chemical)			
Liquid soap (like dishwashing liquid)**				✓								
Chlorine (liquid bleach, dry powder, etc.) diluted to 0.5%		✓						✓ (if chemical with chlorine)				
Activated glutaraldehyde 2.4%								✓ (if chemical with glutaraldehyde)				
White vinegar 3 to 5%				Special circumstances apply								
Small brush (toothbrush or small bottle brush)				✓								
Toothpick				✓								
Clean gauze or cloth (used wet) [†]		✓		✓								
Clean gauze or cloth (used dry) [†]						✓ (if wiping dry)						
Sterile gauze (used dry)										✓ (if wiping dry)		
Steam sterilizer (autoclave)							✓					
Muslin or other porous cloth							✓ (if wrapping equipment)					
Linen ties or masking tape							✓ (if wrapping equipment)					
Boiling apparatus								✓ (if boiling)				
Steamer (not to be confused with steam sterilizer)								✓ (if steaming)				

**Enzymatic cleaner can be used for the CLEANING step, but it is not a disinfectant and cannot be used for HLD.¹⁰

[†]Use only new, clean gauze or cloth where indicated. Never use any piece of gauze or cloth that was previously used for patient care or for cleaning other areas. Never use cotton wool for cleaning or drying. It can leave behind fibers that interfere with sterilization or high-level disinfection.

CHOOSE EITHER STERILIZATION OR HIGH-LEVEL DISINFECTION (HLD)												
MATERIALS/ EQUIPMENT	PREPARA-TION	IMMEDIATE PRE-CLEAN-ING	DISASSEM-BLY	CLEANING	RINSING AFTER CLEANING	DRYING AFTER CLEANING	STERILIZA-TION	HLD PROCESS			INSPECTION/ FUNCTION TESTING/ REASSEMBLY	STORAGE
								HLD	RINSING AFTER CHEMICAL HLD	DRYING AFTER HLD		
Wire mesh dome						✓ (if air drying)				✓ (if air drying)		
High-level disinfected storage container (plastic or metal) with lid												✓ (if storing in container)
Sterile (autoclaved) linen												✓ (if storing in linen)

APPENDIX 3

Cleaning Reusable Personal Protective Equipment

Disposable personal protective equipment (PPE) should be discarded after use following the health facility policies and guidelines for disposal. Reusable PPE should be cleaned according to the manufacturer’s instructions, according to the health facility’s policy, or can be cleaned using the following guidance.¹²

Caps and masks: Wash with soap and hot water and rinse with clean water. Air or machine dry. Store in a clean container with a well-fitting lid or in a clean plastic bag.

Eye protection and aprons (heavy plastic or rubber): Wipe with chlorine solution 0.5% and rinse with clean water between each procedure or each time they are taken off. At the end of the shift or when visibly soiled, wash with liquid soap and water and rinse with clean water. Air or towel dry.

Protective footwear (rubber shoes or boots): At the end of the shift or when visibly soiled, wipe with chlorine solution 0.5% and rinse with clean water. Wash with liquid soap and water and then rinse with clean water. Air or towel dry.

Surgical or utility gloves: Wipe outside of gloves with chlorine solution 0.5%, wash in soapy water, and rise in clean water.

Surgical gloves should be sterilized or high-level disinfected before further use.

Sterilization:	Dry inside and outside of gloves thoroughly then use autoclave to sterilize gloves.
High-level disinfection:	Use one of the following methods to high-level disinfect: <ul style="list-style-type: none">• Dry inside and outside of gloves thoroughly then soak in chlorine solution 0.5% for 20 minutes and rinse completely in boiled water. Dry thoroughly before use.• Steam gloves for 20 minutes. Dry thoroughly before use.

NOTE: Exam gloves should be discarded after single-use.

APPENDIX 4

Proper Chemical Care and Storage

Labeling chemical containers

- All chemicals should be properly labeled with their name, chemical concentration, and the date that the chemical was opened.
- Do not use expired chemicals.
- Do not refill a commercial chemical container with either the same chemical or a different chemical. Refilling containers could lead to misinformation about the contents, the chemical concentration, or the true expiration date. Further, refilling a container with a different chemical could cause a harmful chemical reaction.

Safe practices/storage recommendations

- Chemicals should be stored in appropriately closed containers.
- Chemicals should never be stored on the floor or higher than eye-level.
- Staff should inspect the chemical containers periodically to make sure there is no corrosion or leakage of the contents.

Do not store incompatible chemicals in areas where there exists the possibility of reaction.

General rules:

- Acids and bases should not be stored together.
- Flammable chemicals need to be in an explosion-proof space.
- Water-reactive chemicals should be in a low-humidity environment.
- Oxidizing agents should be stored away from flammable and combustible materials. For example, vinegar should never be stored with or near chlorine products.

The table on the next page provides more detailed information on the chemicals and precautions for storage.

Table 1: Chemical characteristics and storage recommendations

Product name	Synonyms	Characteristics	Can be stored next to (will not react)	Cannot be stored next to (will react)	Storage recommendations	Link to the material safety data sheet*
Glutaraldehyde	Pentanedial, Cidex, MetriCide	<ul style="list-style-type: none"> • Irritant • Non-flammable • Not water reactive 	<ul style="list-style-type: none"> • Liquid soap • Vinegar 	Oxidizing agents (sodium and calcium hypochlorite), alkalis	Keep in well ventilated area and away from light	Glutaraldehyde ^a (50%)
Vinegar	Acetic acid	<ul style="list-style-type: none"> • Irritant • Acid • Flammable (class II combustible with flash point between 37.8°C and 60°C) • Not water reactive 	<ul style="list-style-type: none"> • Liquid soap • Glutaraldehyde 	Oxidizing agents (sodium and calcium hypochlorite), reducing agents, metals	Keep away from heat, flame, direct sunlight	Acetic Acid ^b (vinegar) concentrated Acetic Acid ^c (vinegar) 20%
Sodium hypochlorite	Bleach, chlorine bleach, liquid bleach, household bleach, Clorox, JIK	<ul style="list-style-type: none"> • Irritant • Base • Non-flammable • Not water reactive • Oxidizing agent 	<ul style="list-style-type: none"> • Liquid soap • Chlorine powder or tablets 	Acids (vinegar), combustible materials, organic materials	Keep containers dry and away from heat	Sodium Hypochlorite ^d (5% solution)
Calcium hypochlorite	Chlorine powder	<ul style="list-style-type: none"> • Irritant • Base • Non-flammable • Not water reactive • Oxidizing agent 	<ul style="list-style-type: none"> • Liquid soap • Liquid bleach 	Acids (vinegar), combustible materials, organic materials, moisture	Keep containers dry and away from heat	Calcium Hypochlorite ^e (100%, powder)

*Note that these material safety data sheets do not apply to all concentrations/forms of the chemicals described in this guide.

^a <http://www.sciencelab.com/msds.php?msdsid=9924161>

^b <https://www.sciencelab.com/msds.php?msdsid=9922769>

^c http://www.columbus.k12.wi.us/cms_files/resources/Vinegar.pdf

^d <http://www.sciencelab.com/msds.php?msdsid=9925000>

^e <https://www.sciencelab.com/msds.php?msdsid=9927478>

APPENDIX 5

Dilution for Liquid Bleach (Sodium Hypochlorite) to Create a 0.5% Solution¹²

- Always wear appropriate personal protective equipment when handling chemicals.
- Use only room temperature water to dilute chlorine. Hot water will cause chlorine to degrade more quickly.
- Use only plastic containers to prepare the chlorine solution to avoid rusting and/or other chemical interactions.

To prepare a chlorine solution 0.5% with liquid bleach:

STEP 1: Identify the available chlorine in the bottle at hand that will be used to prepare the solution. See **Figure 1** for examples.

STEP 2: Once the available chlorine in the bottle has been identified, use **Table 1** below to determine how many parts of water are needed to add to each part of bleach.

If the concentration of available chlorine in the product is not listed in **Table 1**, use the formula in **Box 1** to calculate the appropriate dilution.

STEP 3: Use clean and clear water only (if the water is not clear, filter the water first by following the instructions for Clean Water Preparation on **page 15** in the main body of the text).

STEP 4: Using a measuring cup, measure and pour the needed parts of water and then the needed parts of bleach into the plastic container selected for this solution.

STEP 5: Stir the solution well with a clean plastic utensil.

STEP 6: Once prepared, cover the container and label it with the name of the solution ("chlorine solution 0.5%") and the date and time it was prepared.



Figure 1. Examples of how available chlorine information is displayed on household bleach bottles.

Photo Credits: PATH/Manjari Quintanar Solares

These two bottles of household bleach are from the same manufacturer, are sold under the same brand name, and are both available in the same country. However, they contain different amounts of available chlorine. The bottle on the left contains 3.85% available chlorine, while the bottle on the right contains 6% available chlorine. Different amounts of water are required to dilute each of these products to achieve a 0.5% solution.

Table 1. Parts of water needed to dilute different concentrations of liquid bleach to prepare a 0.5% solution.

% available chlorine in liquid bleach (sodium hypochlorite)	Parts water needed for ONE part bleach*
2.4%	4
3.5%	6
3.6%	6
5%	9
6%	11
8%	15
10%	19
15%	29

Note: In some countries, % available chlorine is listed as chlorometric degrees (or "° chlorum"). One ° chlorum is equal to approximately 0.3% available chlorine. Therefore 48° chlorum is about 15% available chlorine (48 x 0.3 = 14.4%).

* "Parts" may be cups, glasses, bottles, etc.

BOX 1

If the concentration of available chlorine that will be used is not listed in the table above, use the following formula to determine total parts (TP) water to be added to each part of liquid bleach:

$$\text{TP WATER FOR EACH PART BLEACH} = \left[\frac{\% \text{ CHLORINE IN LIQUID BLEACH}}{0.5\%} \right] - 1$$

Example using the formula: Make a chlorine solution 0.5% from a concentrated solution containing 3.85% available chlorine.

STEP 1: Calculate TP $\text{TP} = \left[\frac{3.85\%}{0.5\%} \right] = 7.7 \rightarrow 7.7 - 1 = 6.7$ **TOTAL PARTS WATER (ROUND UP TO 7)**

STEP 2: Mix 1 part of concentrated bleach solution 3.85% with 7 parts water. Stir well.

APPENDIX 6

Dilution for Dry Bleach Powder/Tablets to Create a 0.5% Solution¹²

- Always wear appropriate personal protective equipment when handling chemicals.
- Use only room temperature water to dilute chlorine. Hot water will cause chlorine to degrade more quickly.
- Use only plastic containers to prepare the chlorine solution to avoid rusting and/or other chemical interactions.

Dry bleach powder can come as calcium hypochlorite powder, chloramine tablets, or sodium dichloroisocyanurate (NaDCC) tablets. To prepare a chlorine solution 0.5% with dry bleach powder:

STEP 1: Identify the available chlorine in the powder container or tablets that will be used to prepare the solution. See **Figure 1**.

STEP 2: Once the amount of available chlorine has been identified, use **Tables 1 and 2** below to determine how much powder or how many tablets will be needed for each liter of water.

Calcium hypochlorite powder is usually measured by weight, but can also be measured by tablespoons and teaspoons. In some facilities, the calcium hypochlorite powder may be pre-measured by the pharmacy and sent to the unit in small packets. Use whichever method is available. If the concentration of available chlorine in the product is not listed in the tables on the next page, use the formula in **Box 1** to calculate the appropriate dilution.



Figure 1. Example of how available chlorine information might be displayed on a dry bleach powder container.

STEP 3: Use clean and clear water only (if the water is not clear, filter the water first by following the instructions for Clean Water Preparation on **page 15** in the main body of the guidance).

STEP 4: Add the measured bleach powder or tablets into the plastic container selected for this solution and then with a measuring cup, measure and pour the needed parts of water.

STEP 5: Stir the mixture well with a clean plastic utensil to dissolve the powder. Be aware that when using chlorine powder some precipitate (usually a calcium sediment) will fall to the bottom of the container. This sediment will not dissolve completely.

STEP 6: Once prepared, cover the container and label it with the name of the solution ("chlorine solution 0.5%") and the date and time it was prepared.

STEP 7: After the solution has sat for some time, sediment may have settled on the bottom of the container. Do not stir the solution again before use.

Calcium hypochlorite powder is usually measured by weight, but can also be measured by tablespoons and teaspoons (see **Tables 3 and 4**). In some facilities, the calcium hypochlorite powder might be pre-measured in the pharmacy and sent to the unit in small packets. Use whichever method is available in the facility.

Table 1. Grams of calcium hypochlorite **powder** needed per liter of water to prepare a 0.5% solution.

% available chlorine in calcium hypochlorite powder	Options to measure calcium hypochlorite powder	
	Grams of calcium hypochlorite powder needed per liter of water (requires a weighing scale)	Heaped tablespoons of calcium hypochlorite powder needed per liter of water
70% available chlorine	7.1 g/L ^a	0.5 heaped tablespoon/L ^b
35% available chlorine	14.2 g/L ^a	1 heaped tablespoon/L ^b

^a Read as x grams of powder per liter of water. Example: 7.1 grams of calcium hypochlorite powder (70% available chlorine) mixed with 1 liter of water.

^b Read as x heaped tablespoons of powder per liter of water. Example: 1 heaped tablespoon of calcium hypochlorite powder (35% available chlorine) mixed with 1 liter of water.

Table 2. **Tablets** needed per liter of water to prepare a 0.5% solution.

Available chlorine in tablets	Tablets needed per liter of water
Chloramine tablets* (1 g of available chlorine per tablet)	20 tablets/L*
NaDCC-based tablets (1.5 g of available chlorine per tablet)	Follow manufacturer's instructions**

* Chloramine releases chlorine at a slower rate than does hypochlorite. Before using the solution, be sure the tablet is completely dissolved.

**Information on existing presentations and dilution instructions for NaDCC was limited at the time this document was written.

BOX 1

If the concentration of available chlorine that you have is not listed in the table above, use the following formula to determine grams of calcium hypochlorite that you will need to add to each liter of water. This method requires a precision weighing scale.

$$\text{GRAMS/LITER} = \left[\frac{0.5\%}{\% \text{ CHLORINE IN DRY BLEACH POWDER}} \right] \times 1000$$

Using this formula to determine grams of calcium hypochlorite powder needed, mix measured amount of bleach powder with 1 liter of water.

Example: Make 5 liters of a chlorine solution 0.5% from calcium hypochlorite powder with 35% available chlorine.

STEP 1: Calculate grams of powder / liter of water

$$\left[\frac{0.5\%}{35\%} \right] \times 1000 = 14.2 \text{ g/L}$$

STEP 2: Calculate total grams of powder required for 5 liters of water.

$$14.2 \text{ g/L} \times 5 \text{ L} = 71 \text{ g of calcium hypochlorite powder.}$$

STEP 3: Add 71 g of calcium hypochlorite powder to 5 liters of water. Stir well.

Table 3. Calculation of volume of calcium hypochlorite powder (70%) needed to prepare a 0.5% solution.

	Amount of calcium hypochlorite containing 70% available chlorine needed to make 0.5% solution		
Water	Tablespoons (heaped)	Teaspoon equivalent (heaped)	Tablespoons + teaspoons equivalent (heaped)
1 liter	0.5 tablespoon	1.5 teaspoons	0 tablespoons + 1.5 teaspoons
2 liters	1 tablespoon	3 teaspoons	
3 liters	1.5 tablespoons	4.5 teaspoons	1 tablespoon + 1.5 teaspoons
4 liters	2 tablespoons	6 teaspoons	
5 liters	2.5 tablespoons	7.5 teaspoons	2 tablespoons + 1.5 teaspoons
6 liters	3 tablespoons	9 teaspoons	
7 liters	3.5 tablespoons	10.5 teaspoons	3 tablespoons + 1.5 teaspoons
8 liters	4 tablespoons	12 teaspoons	
9 liters	4.5 tablespoons	13.5 teaspoons	4 tablespoons + 1.5 teaspoons
10 liters	5 tablespoons	15 teaspoons	

Table 4. Calculation of volume of calcium hypochlorite powder (30% or 35%) needed to prepare a 0.5% solution.

	Amount of calcium hypochlorite containing 30% or 35% available chlorine needed to make 0.5% solution	
Water	Tablespoons (heaped)	Teaspoon equivalent (heaped)
1 liter	1 tablespoon	3 teaspoons
2 liters	2 tablespoons	6 teaspoons
3 liters	3 tablespoons	9 teaspoons
4 liters	4 tablespoons	12 teaspoons
5 liters	5 tablespoons	15 teaspoons
6 liters	6 tablespoons	18 teaspoons
7 liters	7 tablespoons	21 teaspoons
8 liters	8 tablespoons	24 teaspoons
9 liters	9 tablespoons	27 teaspoons
10 liters	10 tablespoons	30 teaspoons

NOTE about chlorine powder: After stirring calcium hypochlorite powder into the water, a precipitate (usually calcium sediment) may fall to the bottom of the container. This calcium sediment will not dissolve. Do not stir the solution again. Further stirring will cause sediment to coat the equipment.

APPENDIX 7

Tables to Determine Time and Temperature Needed for Steam Sterilization (Autoclave)

The following tables are adapted from the United States Food and Drug Administration³² and have not been specifically validated for resuscitation devices. NOTE: Higher temperatures shorten lifespan of plastic components that are not of the best quality material or are not processed very accurately.

Table 1. Cycle times for gravity-displacement steam sterilization cycles.

Item	Exposure Time at 121°C (250°F)	Exposure Time at 132°C (270°F)	Exposure Time at 135°C (275°F)	Minimum Drying Times
Wrapped bag, mask, and suction device	30 minutes	15 minutes		15–30 minutes
			10 minutes	30 minutes
Unwrapped bag, mask, and suction device (in a load with other nonporous instruments)		3 minutes	3 minutes	0–1 minutes
Unwrapped bag, mask, and suction device (in a load with other porous items)		10 minutes	10 minutes	0–1 minute

Table 2. Cycle times for prevacuum (dynamic-air-removal) steam sterilization cycles

Item	Exposure Time at 132°C (270°F)	Exposure Time at 135°C (275°F)	Minimum Drying Times
Wrapped bag, mask, and suction device	4 minutes		20–30 minutes
		3 minutes	16 minutes
Unwrapped bag, mask, and suction device (in a load with other nonporous instruments)	3 minutes	3 minutes	N/A
Unwrapped bag, mask, and suction device (in a load with other porous items)	4 minutes	3 minutes	N/A

Sterilization (Autoclave) Log for Neonatal Resuscitation Equipment

[illegible]

APPENDIX 9

High-Level Disinfection Log for Neonatal Resuscitation Equipment

[illegible]

HLD = High-level disinfection

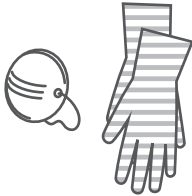
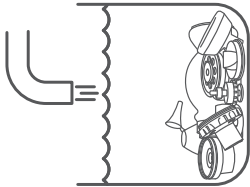

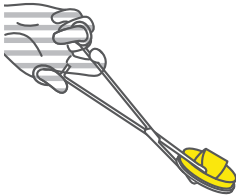
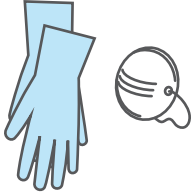
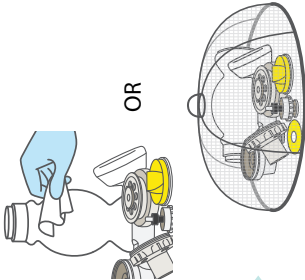
APPENDIX 10

Once you have completed the first reprocessing steps:

- ☒ Preparation
- ☒ Pre-cleaning
- ☒ Disassembly
- ☒ Cleaning
- ☒ Rinsing After Cleaning

BOILING for High-level Disinfection

BOIL the equipment by following these steps:

<div>1</div> <div></div> <div>Wear clean exam or utility gloves and a mask.</div>	<div>2</div> <div></div> <div>Add clean water to the boiling container and submerge all equipment. There should be at least 2.5 cm of water above the equipment. Close the lid.</div>	<div>3</div> <div></div> <div>Bring water to a rolling boil. Once water reaches a rolling boil, boil all items for 20 minutes. Record start and end time.</div>	<div>4</div> <div></div> <div>Use high-level disinfectant forceps to remove equipment from boiling water immediately. Never leave boiled instruments in water that has stopped boiling.</div>	<div>5</div> <div></div> <div>Put on sterile or high-level disinfectant gloves and a mask before touching the equipment.</div>	<div>6</div> <div></div> <div>Wipe dry with sterile gauze or air dry in a protected space.</div>
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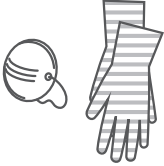
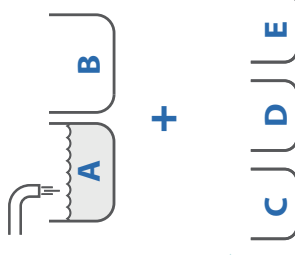
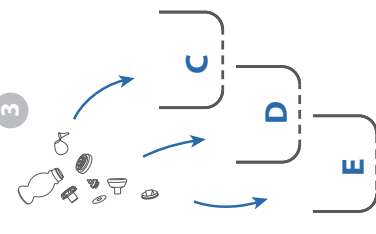
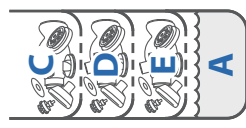
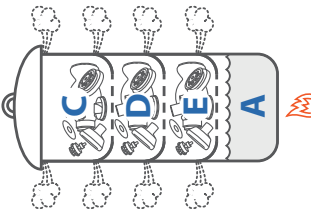
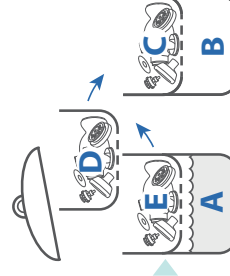


Complete the last reprocessing steps: Inspection/Reassembly/Function Testing/Storage

APPENDIX 11

Once you have completed the first reprocessing steps: ☒ Preparation ☒ Pre-cleaning ☒ Disassembly ☒ Cleaning ☒ Rinsing After Cleaning

STEAMING for High-Level Disinfection (not autoclaving)

STEAM the equipment by following these steps:

<div>1</div> <div></div> <div>Wear clean exam or utility gloves and a mask.</div>	<div>2</div> <div></div> <div>Necessary equipment for cleaning: - 2 steamer pans without holes - 3 pans with holes Fill the bottom of steamer pan A, with approximately 1L of clean water. Place a second empty pan B (without holes) on the counter next to the heat source.</div>	<div>3</div> <div></div> <div>Place the resuscitation equipment in each steamer pan with holes. Do not overfill the pan. Repeat this process until steamer pans have been filled.</div>	<div>4</div> <div></div> <div>Stack the filled steamer pans on top of bottom pan containing water for boiling. Place a tight-fitting lid on the top pan.</div>	<div>5</div> <div></div> <div>Bring water to a rolling boil. Once steam begins to come out between the pans and the lid, steam items for 20 minutes. Record start and end time.</div>	<div>6</div> <div></div> <div>At the end of steaming, remove the top steamer pan C and put the lid on pan D below. Gently shake excess water from pan C and put it onto the empty pan B. Repeat until all steamer pans are restacked onto pan B. Place the lid on the top pan.</div>	<div>7</div> <div></div> <div>Allow equipment to air dry in the steamer pans.</div>	<div>8</div> <div></div> <div>Put on sterile or high-level disinfected gloves and a mask before touching the equipment.</div>
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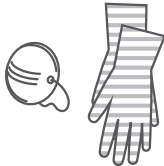
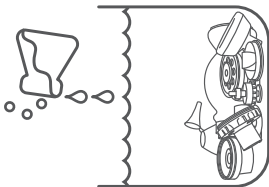
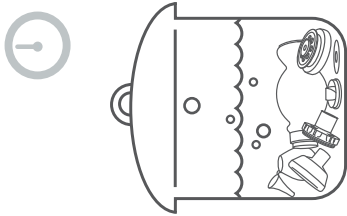
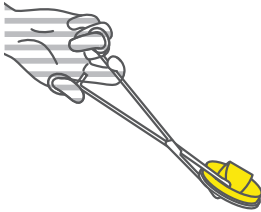


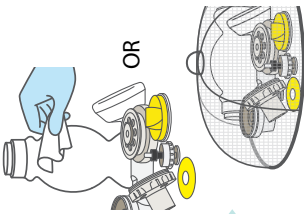
Complete the last reprocessing steps: Inspection/Reassembly/Function Testing/Storage

APPENDIX 12

Once you have completed the first reprocessing steps: ☒ Preparation ☒ Pre-cleaning ☒ Disassembly ☒ Cleaning ☒ Rinsing After Cleaning ☒ Drying

CHLORINE 0.5% for High-Level Disinfection

SOAK the equipment in CHLORINE by following these steps:

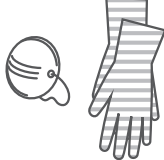
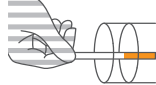

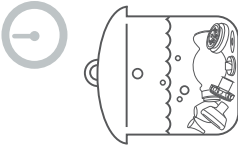
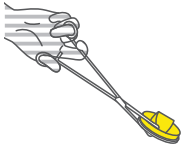


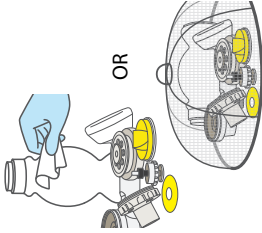
<div>1</div> 	<div>2</div> 	<div>3</div> 	<div>4</div> 	<div>5</div> 	<div>6</div> 	<div>7</div> 	<p>Wear clean exam or utility gloves and a mask.</p> <p>Fully submerge equipment in chlorine solution 0.5%. There should be at least 2.5 cm of solution above the equipment. Cover the container.</p> <p>Soak for 20 minutes. Record start and end time.</p> <p>Use high-level disinfectant forceps to remove equipment from the chlorine solution.</p> <p>Put on sterile or high-level disinfectant gloves and a mask before touching the equipment.</p> <p>Rinse equipment in three separate containers of boiled water for 1 minute each.</p> <p>Wipe dry with sterile gauze or air dry in a protected space.</p>
Complete the last reprocessing steps: Inspection/Reassembly/Function Testing/Storage							

APPENDIX 13

Once you have completed the first reprocessing steps: ☒ Preparation ☒ Pre-cleaning ☒ Disassembly ☒ Cleaning ☒ Rinsing After Cleaning ☒ Drying

ACTIVATED GLUTARALDEHYDE 2.4% for High-Level Disinfection

SOAK the equipment in GLUTARALDEHYDE by following these steps:

<div>1</div> <div></div> <div>Wear clean exam or utility gloves and a mask.</div>	<div>2</div> <div></div> <div>Test the solution using the glutaraldehyde manufacturer's test strip prior to each use.</div>	<div>3</div> <div></div> <div>Fully submerge equipment in activated glutaraldehyde 2.4%. There should be at least 2.5 cm of solution above the equipment. Cover the container.</div>	<div>4</div> <div></div> <div>Soak for the time specified in the chemical manufacturer's instructions. Record start and end time.</div>	<div>5</div> <div></div> <div>Use high-level disinfected forceps to remove equipment from glutaraldehyde solution.</div>	<div>6</div> <div></div> <div>Put on sterile or high-level disinfected gloves and a mask before touching the equipment.</div>	<div>7</div> <div></div> <div>Rinse equipment in three separate containers of boiled water for 1 minute each.</div>	<div>8</div> <div></div> <div>Wipe dry with sterile gauze or air dry in a protected space.</div>
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Complete the last reprocessing steps: Inspection/Reassembly/Function Testing/Storage

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